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The Myth of the Anticommons

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May 31, 2007

Executive Summary:

The theory called the *tragedy of the anticommons* was put forth in 1998 and claimed that over-patenting of research in the field of biotechnology was hindering research and development of new innovative treatments. Although no empirical evidence was cited, the theory quickly gained traction.

This paper examines the theory from both a theoretical and empirical basis. From a theoretical perspective, we find that the geographical interpretation that has been implied is too limited.

On the empirical side, rather than finding an industry unable to continue to find innovative therapies due to a patent thicket, we find an industry that is actively engaged in discovering and inventing innovative therapies. Specifically, we find that:

1. Since 1998 R&D of publicly traded biotech companies has increased over 60%.
2. From 1995 – 2005 the amount of venture capital funding for biotechnology companies has increase 300%.
3. Employment has increased by 21% since 1998.
4. Annual original INDs received by the FDA, while steady for a number of years, has shown a sharp increase in 2004 and 2005.
5. The number of biological compounds entering preclinical trials in 2005 was 37% higher than the number entering trials in 1998.
6. None of the academics surveyed reported abandoning a line of research due to patents on knowledge inputs.

Thus, we conclude that there is neither theoretical support nor empirical evidence to support the idea of the *tragedy of the anticommons*.

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Myth of the Anticommons:

I. Introduction:

In 1998 Heller and Eisenberg put forth an idea in a paper that suggested that over-patenting was threatening innovation in the biotechnology industry.[1] The idea was called the *tragedy of the anticommons*. The theory posited that, because of the excess number of patents in the biotechnology arena, innovation would be stifled due to an inability to conduct research without patent infringement. Although no empirical evidence was cited, the idea quickly gained a good deal of attention and traction.

This paper examines the theory of the anticommons from both a theoretical and empirical perspective. The paper finds that the theoretical construct, upon which the theory of anticommons is based, is too simplistic to adequately characterize the biotechnology world. Further, though a number of metrics are examined, none of the metrics empirically support the idea that there is over-patenting in the biotechnology industry.

The paper is arranged as follows. Section one contains a brief overview of the economics of patents. Section two provides an overview of the theory of the *tragedy of the anticommons*. Section three discusses the theoretical shortcomings of the theoretical construct. Section four examines the empirical evidence. A brief conclusion follows.

II. Overview of the Economics of Patents:[2]

The idea underpinning the US Patent system is the balance between giving incentives to inventors and giving society broad access to innovation. Abraham Lincoln may have put it best when he said, "The Patent System added the fuel of interest to the fire of genius." On one hand inventors need to be rewarded for the time and effort that they have put into their inventions. Thus, society grants patents to inventors which bestow a property right to the individual inventor. The invention belongs to the inventor and can not be copied or used without the permission of the inventor. The result of this exclusive ownership is that the price of the invention that is able to be charged is higher than it would be in a competitive market, and therefore, the inventor makes a higher profit for the invention that has been patented.

The ability to charge the higher price for their innovative products provides the innovators with an incentive to develop innovative products. Without the incentive

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[1] Heller, M.A. and Eisenberg, R.S. "Can Patents Deter Innovations? The Anticommons in Biomedical Research." *Science* Vol **280**. 1 May 1998.

[2] The discussion presented in the paper is a simplified overview of the patent system in order to facilitate an examination of whether there is evidence of the *tragedy of the anticommons.* Please refer to http://www.bio.org/ip/primer/main.asp for a fuller discussion of the U.S. patent system.

provided by the patent, the pace of innovation would slow because inventors would not be rewarded as much for the time, effort and risk that it took to develop the innovation. Indeed, intellectual property protection has been found to be a significant determinant of economic growth.[3]

The patent system is especially important to the biotechnology industry.[4] Each biopharmaceutical that is brought to market requires on average $1.2 billion in research and development. The cost is high for a number of reasons. The reasons include the number of failures that occur along the way. For every biopharmaceutical that is brought to market, there are approximately10,000 failed attempts. In addition, the time to go through clinical development and regulatory approval to market for the biopharmaceutical is 97.7 months on average.[5, 6] Finally, the cost of the clinical trials is quite high and has risen substantially in the past decade. On average the cost of research and development rose 7.5% above the annual rate of inflation during the 1990s, the latest years for which figures are available.[7] Patents granted on a biotechnological innovation allow the inventors to recoup the research and development costs which have been invested.

III. Overview of the Anticommons Argument:

As has been discussed, patents are central to the development of innovative therapies in the biotechnology industry. However, in 1998 an idea was put forth that suggested that patents, instead of encouraging innovation, had the potential to actually stifle innovation in the biotechnology industry. This stifling of innovation was called the *tragedy of the anticommons*.[8] The authors posit that innovation may be stifled if there are too many owners who may exclude others from a scarce resource. Specifically, if there are too many patent holders of upstream technology, they may inhibit downstream innovation because of transaction costs and strategic behaviors. Imagine that a biotechnology

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[3] Gould, D. M. and Gruben W. C. "The role of intellectual property rights in economic growth." *Journal of Development Economics* Vol **48** (1996) 323 – 350.

[4] See for example, Cohen, W, M., Nelson R. R. and Walsh, J. P. "Protecting their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)." NBER Working Paper 7552. February 2000.

[5] DiMasi, Joseph A. and Henry G. Grabowski. "The Cost of Biopharmaceutical R&D: Is Biotech Different?" *Managerial and Decision Economics*. Forthcoming.

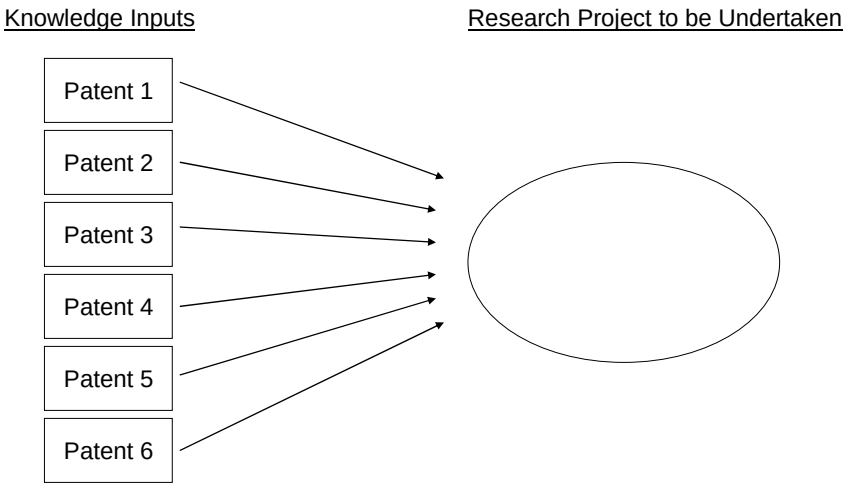
[6] Note: This does not include pre-clinical time of development.

[7] DiMasi, J. A., Hansen, R. W. and Grabowski, H. G. "The price of innovation: new estimates of drug development costs." *Journal of Health Economics* 22 (2003).

[8] Heller, M. A. and Eisenberg, R. S. "Can Patents Deter Innovations? The Anticommons in Biomedical Research." *Science* Vol **280**. 1 May 1998.

company seeks to do research in a particular area to bring an innovative therapy to market and that in order to do research in this area the company must use a set of knowledge inputs. Further, suppose that each of the knowledge inputs has been patented by a different company. In order for the biotechnology company to proceed with the research, it must first receive permission from each of the patent holders to use the patent holder's knowledge input for its research.

Figure 1:



In this case the company would need to obtain permission from 6 different parties before it could undertake the research project

Getting permission may take considerable time and may require considerable money. Thus, the research to bring an innovative therapy to market may be delayed, may cost more or may not take place if the company can not obtain permission from all of the upstream patent holders. In this scenario one patent holder in the set of knowledge inputs could suppress the research by not granting permission for the biotechnology company to use its patented input.

IV. Theoretical Shortcomings of the Anticommons:

The theory outlined above is appealing for its simple elegance. However, the simplicity of the argument is one of its short comings. An implicit part of the argument is that there is a scarcity to the biological commons akin to a geographical scarcity. Indeed, in responding to Heller's and Einsberg's call for a formal economic model to be developed,

Buchanan and Yoon developed an economic model and illustrated it geometrically.[9] Further, in another paper that discusses the *tragedy of the anticommons* Scherer states, "The problem is analogous to conditions on the Rhine River during the 18th Century. Over the 85-kilometer stretch between Mainz and Koblenz in 1780, there were nine toll stations…"[10] The result of the excessive number of tolls was a significantly lower amount of traffic on the river.

The geographic analogy is appealing but is flawed when applied to the biotechnology industry. In the examples above, there is a single starting point and a single ending point. In addition in the Rhine River analogy there is only one route from the starting point to the ending point. However, the "geography" in the biopharmaceutical world is much more complex than geography that is described in the world of the anticommons. In biotechnology world there are many starting points and many routes that will lead to the desired ending point, which in this case is an innovative therapy. In applying the "geography" of the biopharmaceutical world to the Rhine River analogy, imagine that a shipper wants to transport good from Mainz to Koblenz but is faced with having to go through nine toll stations on the river. Whereas in the 18th century, the shipper had no other option but to traverse the river, in the 21st century biotechnology world, the shipper has alternative routes, such as roads, rail or air. Thus, the shipper can reach the desired ending point by going around the river tolls.[11]

The idea of going around a toll is well known in the biopharmaceutical industry, as well as other industries, and is called inventing around a patent. An illustrative example is the class of pharmaceuticals called statins, which are medicines designed to lower blood cholesterol levels. In this case, the desired endpoint is a lower blood cholesterol level. According to the geographical example above, there is only one route to the desired endpoint and thus, one would expect only one statin to be on the market. However, there are more than five statin products on the market presently. The statins are but one class among many therapeutic classes of pharmaceuticals in which there are two or more products. There are multiple products in clinical testing for the treatment of breast cancer that utilize a variety of mechanisms of action. Some of these products' mechanisms of action overlap with the mechanisms of action utilized by other products.[12] Likewise, there are multiple products being developed for the treatment of chronic myeloid

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[9] Buchanan, J. M. and Yoon, Y. J. "Symmetric Tragedies: Commons and Anticommons." *Journal of Law and Economics* Vol. **43**, No. **1**. (April 2000).

[10] Scherer, F. M. "The Economics of Human Gene Patents." *Academic Medicine* Vol. **77**, No. **12** (December 2002) Part 2, p. 1363.

[11] Epstein, R. A. and Kuhlik, B. N. "Is there a Biomedical Anticommons?" *Regulation* Summer 2004.

[12] Waltz, Emily. "GlaxoSmithKline Cancer Drug Threatens Herceptin Market." Nature Biotechnology Vol. 23, No. 12. December 2005.

leukemia.[13] Therefore, one can conclude that the geography of the biopharmaceutical world is much richer and more complex than the geography posited by the world of the anticommons.

V. Empirical and Experiential Evidence and the Anticommons:

While the discussion above showed that the geographical assumption of the anticommons theory is too limited, that does not demonstrate that the *tragedy of the anticommons* is not occurring. We can not categorically prove that there is no *tragedy of the anticommons*. To do so would require an examination of a world without patents that does not exist. However, we are able to examine the world as it is and determine what evidence, if any, exists for over-patenting. If over-patenting were occurring in the biotechnology industry, one would expect that fewer innovative therapies would be brought to market. However, given that the timeline to bring a product to market is approximately 12 years from time of patent, it is likely too soon to examine number of innovative therapies for evidence of the anticommons. Therefore, we examine the inputs that produce the innovative therapies. That is, we examine the amount of research and development that is occurring, the result of that research and development and the experience of companies and researchers in the industry. If the *tragedy of the anticommons* is occurring, one would expect the following:

1. The amount of research and development would decline
2. *Ceteris paribus* fewer potential innovative therapies would be tested
3. Companies and researchers would clamor for a public policy remedy

We examine each of these in turn.

1. The amount of research and development would decline

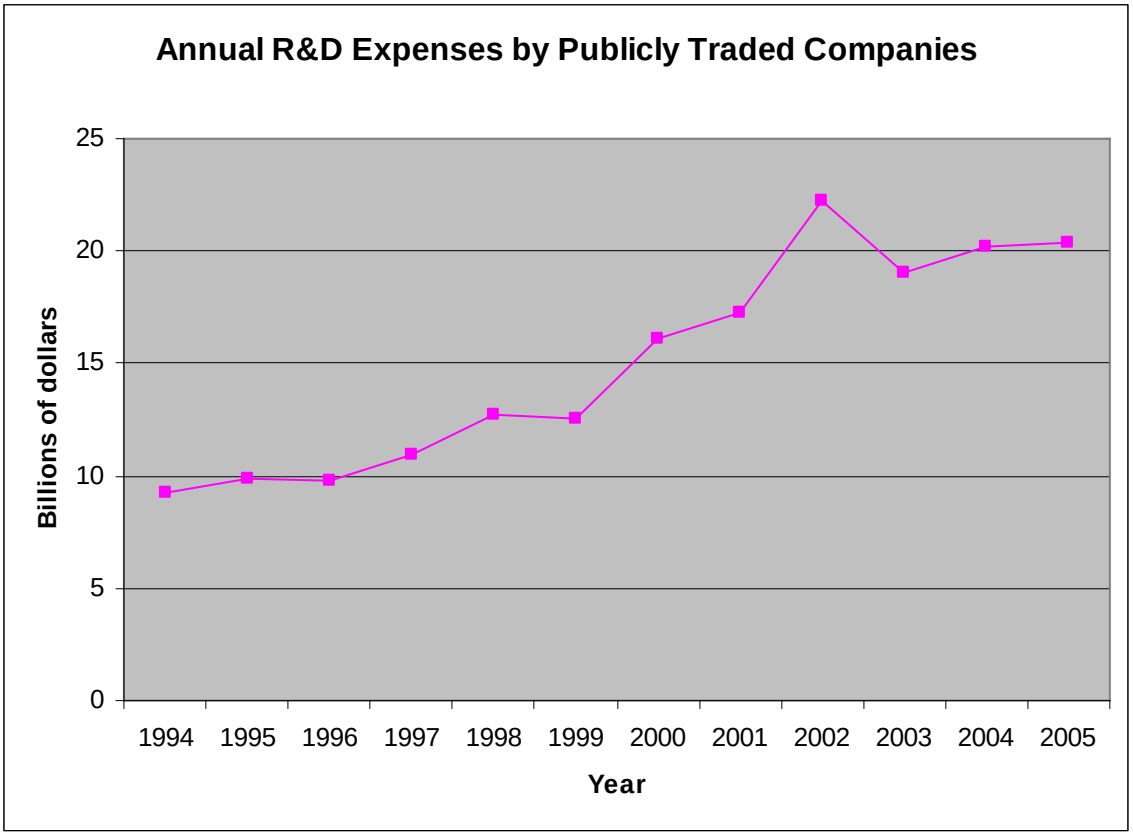
Recent R&D History:

Companies will spend research and development dollars until the point at which it is no longer profitable for them to do so. From a more formal economic stand point, companies will spend until the expected marginal benefit of the research and development (e.g., the expected revenue derived from the research and development) equals the expected marginal cost of the research and development. The idea of the anticommons is that upstream knowledge inputs, which would be used in developing innovative therapies, have been "over-patented" and thus research in these areas is difficult, if not impossible, to do without engaging in patent infringement. The practical effect of this over-patenting is to make research and development more difficult (e.g., costly) to undertake. Thus, one would expect that because the research has become more costly, the amount of research and development undertaken by biotechnology firms

[13] Hampton, Tracy. "Looking Beyond Imatinib." JAMA Vol. 295, No. 4. January 25, 2006.

would decrease. However, if one examines the amount spent on biotechnology research and development, the evidence does not indicate that *tragedy of the anticommons* is occurring.

Figure 2:



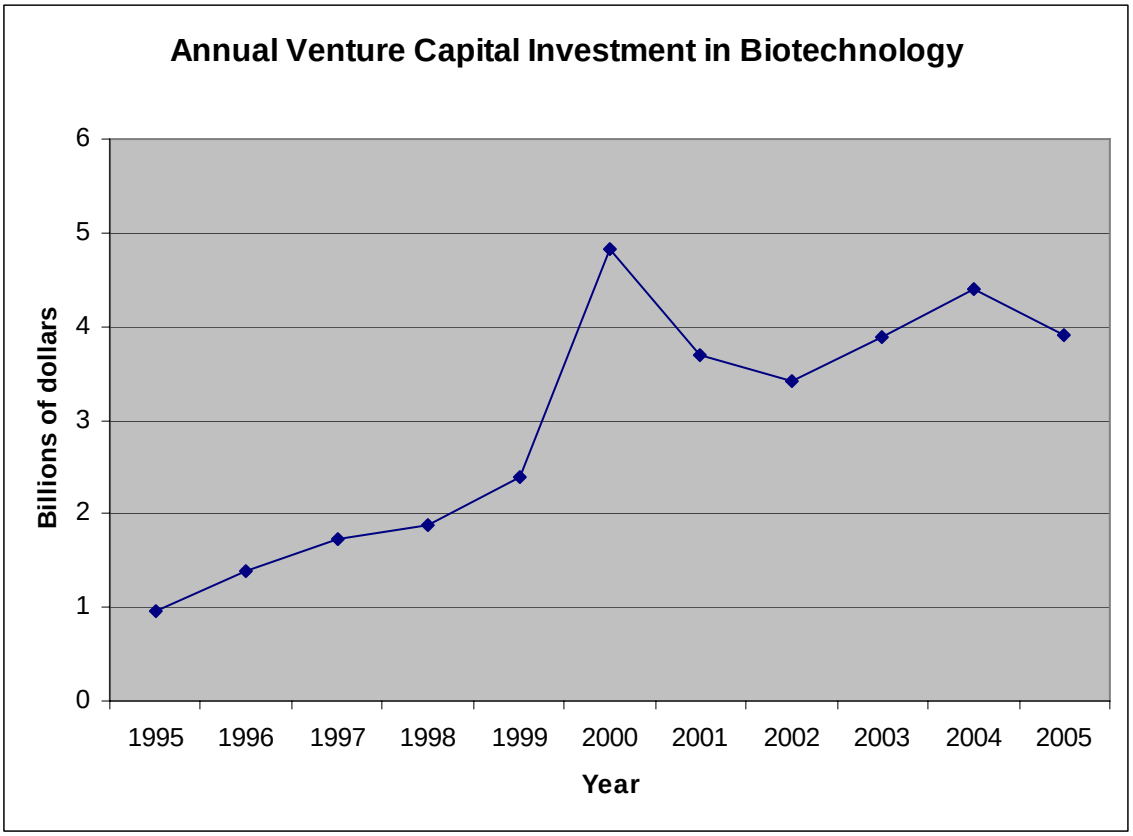
Sources: Ernst & Young LLP, annual biotechnology industry reports, 1993–2006. Financial data based primarily on fiscal-year financial statements of publicly traded companies; constant 2005 dollars.

Figure 2 indicates that the amount of research and development by publicly traded companies in the biotechnology arena has grown substantially over the past decade. Indeed, since 1998 when the *tragedy of the anticommons* was posited, R&D has increased by over 60%.[14]

[14] However, one could argue that perhaps the cost of doing research and development has actually decreased during the time period. If the costs decreased at a faster rate than the cost increase associated with the *tragedy of the anticommons*, one could argue that the investment in research and development would therefore increase. However, according to DiMasi, the cost of research and development of innovative therapies has increased at a rate of 7.5% over and above the cost of inflation during the 1990s. DiMasi J. A., Hansen, R. W. and Grabowski H. G. "The price of innovation: new estimates of drug development costs." *Journal of Health Economics* 22 (2003).

While figure 1 focuses on publicly traded companies, privately held biotechnology companies play a pivotal role in the biotechnology industry.[15] Much of the funding for these companies comes from the venture capital (VC) community. If companies were unable to perform research and development due to the presence of the anticommons, one would expect the VC investment in biotechnology to dry up.

Figure 3:



Source: National Venture Capital Association; constant 2005 dollars

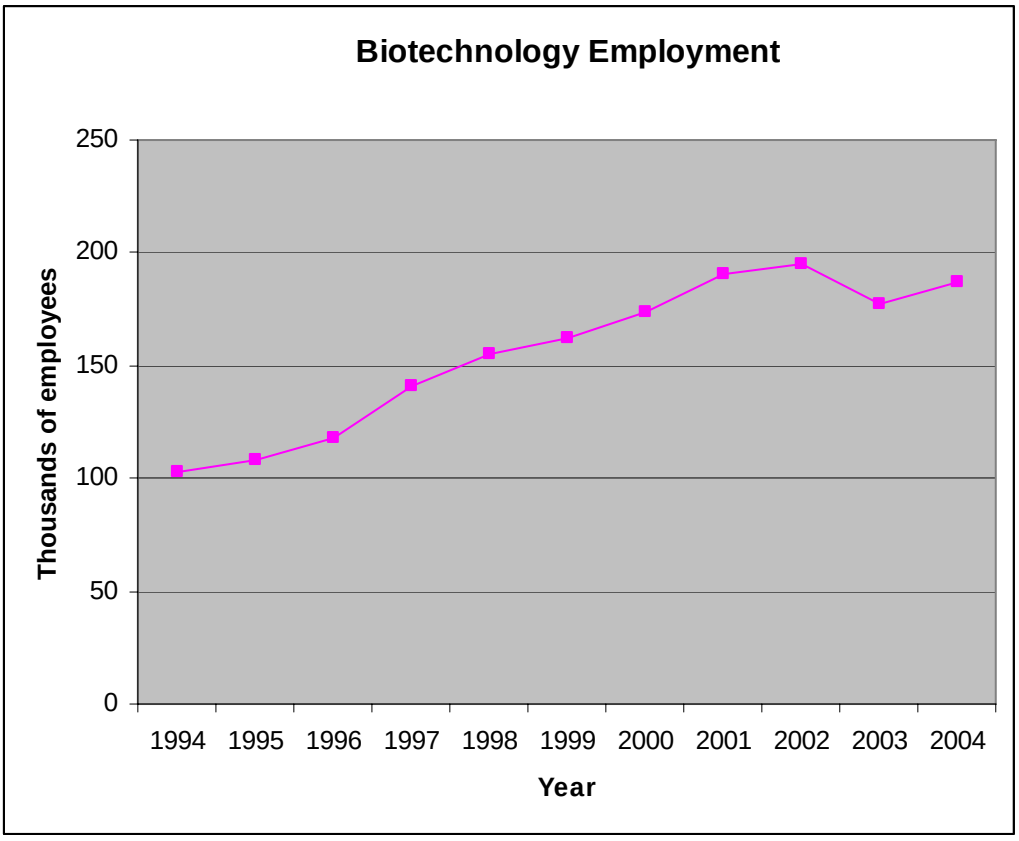
Figure 3 shows that the amount of VC has increased substantially in the past decade. In 2005 the amount of VC funding was almost $4 billion, up 300% from 1995.

Another aspect of research is the number of personnel. If the industry were experiencing a significant slow down due to the *tragedy of the anticommons* and the inability to pursue research on innovative therapies, one would expect that the difficulties of the industry

[15] Indeed, according to figures in Ernst and Young's Beyond Borders 2006 three quarters of the U.S. biotechnology companies in 2005 were privately held.

would be reflected in a decrease in the number of industry employees. However, biotechnology employment has risen over the past decade.

Figure 4:



Sources: Ernst & Young LLP, annual biotechnology industry reports, 1993–2005.

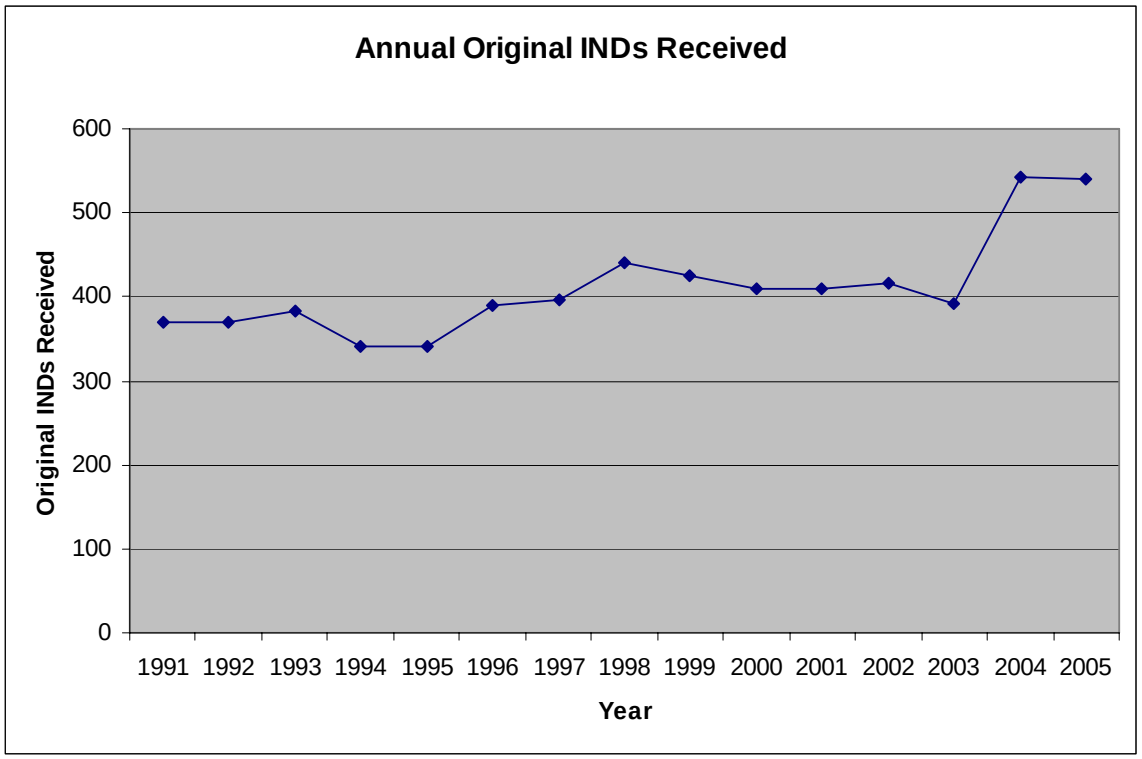
Since 1998, the number of employees has increased by 21%. Thus, instead of seeing what one would expect if an industry were experiencing the *tragedy of the anticommons* – lower research and development and with it falling employment – one observes an industry which is increasing research and development levels and increasing employment.

2. *Ceteris paribus* fewer potential innovative therapies would be tested

If the *tragedy of the anticommons* were occurring one would expect that the R&D that was being undertaken would be less efficient. That is, because so many of the knowledge inputs had patents that needed to be licensed or invented around, the research projects would take longer or the research projects would be abandoned altogether. As a result of the increased difficulty of doing research, the number of innovative therapies would decrease. However, given the long lead time that it takes to research and develop an innovative therapy and bring it to market, approximately 12 years, it may be too early to see evidence of the *tragedy of the anticommons*. Therefore, we examine the number of

annual Investigational New Drug (IND) submissions, which would be affected in a similar way. Because of the shorter timeframe, if the *tragedy of the anticommons* were occurring, one would expect the number to have decreased.[16]

Figure 5:



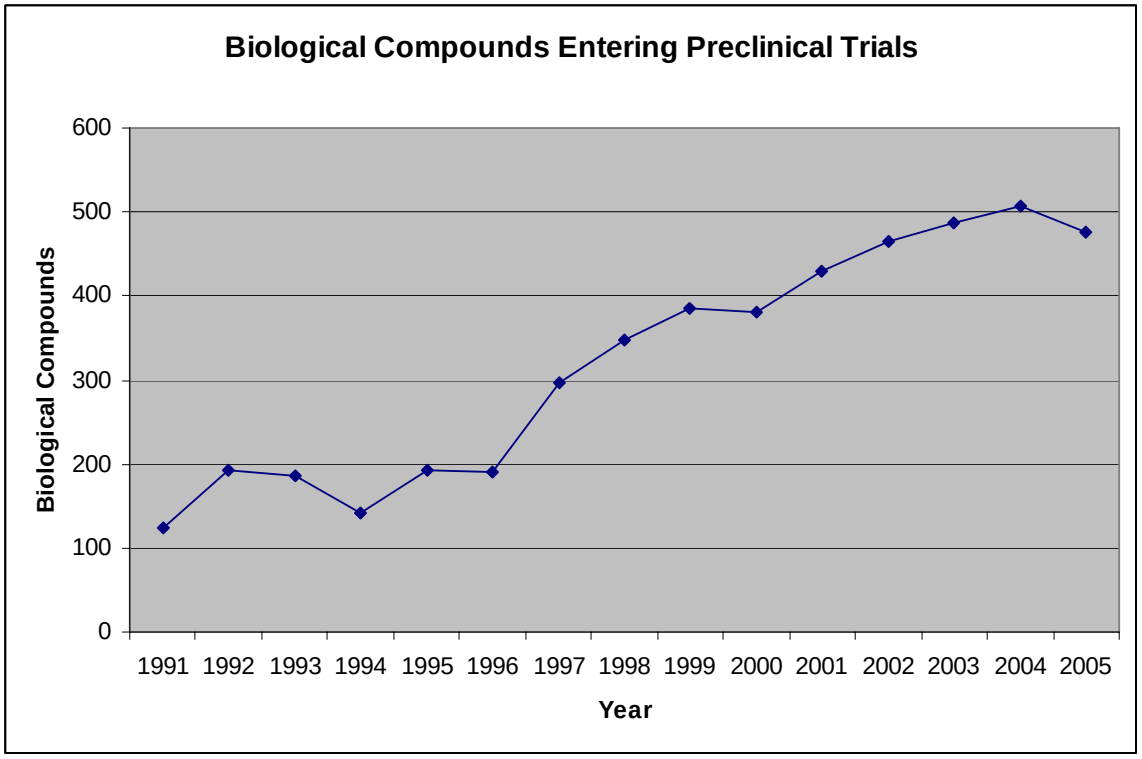
Source: FDA, Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2006/2007

One would expect the number of INDs to drop if the *tragedy of the anticommons* were occurring. One finds a relatively stable number of INDs being originated annually from 1991 – 1998, the seven year time period before the *tragedy of the anticommons* was posited, and a relatively stable number of INDs being originated from 1998 – 2003. However, there is a sharp increase in the number of original INDs received in 2004 and 2005. These years are precisely the time period when one would expect a decrease if over-patenting were starting to occur in 1998. One would expect a decrease in INDs approximately six to seven years after the phenomenon began to occur because pre-clinical testing (that is the time from a drug being patented until it reaches the IND stage) takes on average between 3 – 6 years. If there were an anticommons problem, it would take 3 – 6 years to manifest.

[16] Because biotechnological inputs are used for the development of both small molecule therapies and therapeutic biologics, we examine both in turn.

Next, we examine the number of biological compounds that enter preclinical testing on an annual basis.

Figure 6:



Source: Pharmaprojects, Informa Healthcare

Rather than finding a decrease in the number of biological compounds entering preclinical trials, we find there has been a substantial increase in the number of biological compounds entering preclinical trials both before and after 1998. While the percentage growth has dropped from the 1991 – 1998 to the 1998 – 2005 time periods, in 2005 there were still more than 37% more compounds entering preclinical trials every year than were entering in 1998. This finding is inconsistent with research being stifled or hampered as one would expect to find if the *tragedy of the anticommons* were occurring.

3. Companies and researchers would clamor for a public policy remedy

A substantial number of members of the Biotechnology Industry Organization (BIO), the trade association for the biotechnology industry, are companies who depend on the ability to research and develop innovative therapies. Thus, if there were a *tragedy of the anticommons*, one would expect that BIO would be clamoring for a public policy remedy especially patent reform. However, rather than implying that there is a *tragedy of the anticommons* which is impeding research, BIO's position implies that the patent system encourages innovation. That is, the patent system is not hindering innovation, but rather,

the patent system is allowing companies to engage in research and development of innovative therapies.[17]

The *tragedy of the anticommons* focuses specifically on the patenting of upstream research. However, BIO's position specifically supports the patenting of "novel and useful nucleotide sequences..." BIO also supports patenting research tools which, like nucleotide sequences, are akin to the knowledge inputs that the *tragedy of the anticommons* discusses. Further, BIO's position fundamentally opposes the notion that patents on this broad array of biotechnology inventions are hindering innovation. BIO says unequivocally that it supports patenting of these types of inventions. In addition, it affirms that intellectual property rights are a prerequisite for the commercial success of these companies and for future innovation in these knowledge inputs.

While the discussion above focuses on companies and shows no evidence of the anticommons, one may argue that perhaps the *tragedy of the anticommons* is affecting academic researchers rather than companies. The National Academy of Sciences commissioned a study to examine the issue.[18] Walsh *et al* surveyed 414 academic researchers from universities, non-profits and government labs to examine whether their research had been impacted by patents. The authors found that only 1% of the academic respondents stated that they had experienced delays on their projects of more than a month due to patents on knowledge inputs. None of the academics reported abandoning a line of research due to patents on knowledge inputs.

Thus, neither biotechnology companies nor academic researchers are claiming to be adversely affecting by the patenting that is occurring in the biotechnology arena. Indeed, none of the academic researchers surveyed have abandoned research because of patent issues. Further, biotechnology companies have stated not only are patents not hurting them, but on the contrary the ability to patent is a prerequisite for commercial success.

We find no evidence of a *tragedy of the anticommons* either among companies or among the researchers who work in academic, non-profit or governmental settings.

VI. Conclusion:

The *tragedy of the anticommons* is an elegant and compelling theory. The theory claims, that instead of encouraging innovation as patents have been found to do in the biopharmaceutical industry, the patenting that has been occurring in the 1990s has the potential to hinder innovation. However, as has been discussed, the theoretical construct of the anticommons world is too simplistic to describe the world of biotechnology. We

[17] BIO's Principles for Patent Reform Approved March 29, 2004 Board IP Standing Committee.

[18] Walsh, J. P., Cho, C. and Cohen, W. M. "View from the Bench: Patents and Material Transfers." *Science* Vol **309**. 23 September 2005.

acknowledge that we can not categorically state that there is no *tragedy of the anticommons*. To do so would require an examination of a world without patents that does not exist. However, we are able to examine the world as it is and determine what evidence there exists for over-patenting. Indeed, if over-patenting were occurring, the outcome of this over-patenting would be "fewer useful products for improving human health."[19] Because of the long development time of innovative therapeutic products, we inspect the inputs of those products. The first input is R&D. If there were a *tragedy of the anticommons,* one would expect that the amount of R&D would decline because of the increased difficulty of undertaking research. Yet, we find the exact opposite. R&D in both the publicly traded and privately held biotechnology companies is increasing. Further, we find that the number of people employed in the industry is increasing over time. Next, we inspect the pipelines of biopharmaceutical industry. If the research were becoming more difficult, one would expect that the number of innovative therapies in testing would be decreasing. Rather, we find the opposite. We find that the pipeline of both chemically and biologically based innovative therapies is expanding. Thus, the information that we examine paints a picture of an industry that is growing in terms of research and development with an increasing number of products in the pipeline. The argument could be made that perhaps researchers – either those in industry or in academia - are encountering problems that are not reflected in the R&D figures or in the numbers associated with the product development pipeline. However, the biotechnology industry is strongly supportive of the patent system and contends that it encourages innovation. Thus, industry is not supportive of the idea that over-patenting is occurring and hindering its ability to bring innovative therapies to the marketplace. Further, none of the academic researchers surveyed by Walsh *et al* abandoned their line of research due to patents on knowledge inputs. Therefore, we conclude, based on both empirical and experiential evidence, that there is no support for the idea that a *tragedy of the anticommons* is occurring in the biotechnology industry.

[19] Heller, M. A. and Eisenberg, R. S. "Can Patents Deter Innovations? The Anticommons in Biomedical Research." *Science* Vol **280**. 1 May 1998.