

The pharmaceutical industry maintains a large portion of the private sector in the United States. In fact as one of the most profitable industry in the American economy, *Fortune* magazine named it as the most profitable industry in 1999 due to the net profit margin of 18.6% (median of 5.0).<sup>1</sup> Thus, it can be said that the pharmaceutical industry greatly influences the medical field. The advent of new technologies in genomics after the sequencing of the human genome in 2003 has brought new possibilities to the industry and the public. More informed research can be done to advance the science associated with treating diseases, both viral and bacterial. Furthermore, patents and the idea of patenting genes has become of great importance. Policies, as well as moral views have come under scrutiny as the industry and the government attempt to adapt to the new technology. The impacts of the decisions made in these areas affect not only the researchers and the physicians who are in daily contact with the new technologies, but also the general public as the treatment of diseases becomes transformed by the industry. Thus, to understand the growing field of genomics and the development of new technologies one must first understand the interactions between the pharmaceutical industries, patents, and the burgeoning technology associated with genomics itself.

### ***Pharmaceutical Industry: Past and Present***

It is commonly said that everything is determined by the market. This is especially true here in the United States. For this reason it is not surprising that the leading industry in the United States, the pharmaceutical industry, should have such a large influence on patients' lives and on the development of new treatments. The

approach of pharmaceutical companies, like for any big business is looking toward profit margins and expansion. Their main strategies toward getting the funds to cover the tremendous expenses include different sources such as lobbying lawmakers, fighting to prolong patent protection, targeting drugs which help larger markets, creating demand from patients, and approaching doctors.<sup>2</sup> Developing new drugs and treatments is a time-consuming and expensive venture. To pharmaceutical companies the less needed to produce the drugs the better because the more net profit will be gained. The multi-step process in drug development and proliferation into the market can be broken down into four general steps, including: drug discovery, animal studies, clinical trials, and commercialization, each with unique difficulties and aspects which affect the overall process.<sup>3</sup> This process and its drawn out nature has become the impetus for many pharmaceutical companies to raise costs to the consumers. In particular, the amount of money spent on Research and Development (R&D) is used as a valid excuse by the pharmaceutical industries for increasing prices to the consumers.

Having to put their products under several rounds of costly clinical trials, there are few drugs that actually become released. In addition, this sector contains a large portion of the costs incurred in the development of drugs. For instance, in 2001 it was projected that more than \$30.5 billion (18.5% of sales revenue) was spent on the development of drugs.<sup>2</sup> Some of these discoveries never even fully make it to the medicinal stage, since only 2% become commercial drugs.<sup>2</sup> Thus, the time and energy spent on developing a drug does not correlate to the yields. Furthermore, getting approval from the F.D.A. takes an average of 13 years.<sup>2</sup> Despite the fact that R&D has little to do with the actual cost to

the consumer, it is used by the pharmaceutical companies as justification for the costs and many risks associated with their industry.

Another important part of the drug industry appears to be that in the past few decades the pharmaceutical industry has shifted its focus. With the high costs and large amount of time spent on clinical trials many focus on developing drugs for chronic diseases rather than antibiotics. Logic presents the situation clearly, as producing a drug such as Lipitor™, used daily for many years will allow greater profits while other treatments are still being developed<sup>4</sup>. Furthermore, since the pharmaceutical industry is molded by ten big name companies which hold more than 50% of the sales<sup>4</sup>, smaller companies must also focus on such drugs in order to compete. The concepts behind producing drugs for the masses also come into play with the advent of genomics, since the new technology produces drugs targeting fewer individuals. Only the individuals containing a specific gene can use the drug, helping in the transition away from mass drug production. Nevertheless, the profit margin would still be greater as less time will be spent finding target genes and the drugs produced will be more likely to work.

Specifically, before genomics, \$1 million was spent on creating one drug, but after genomics the costs went down 60%.<sup>3</sup> Also, the percentage of drugs that have gone through the whole innovation process and are released into the market has skyrocketed. Before the advent of genomics only 5% of drugs 20 years ago made it through the entire development process and into the hands of patients, while today that number has reached 20%.<sup>3</sup> This is a direct result of genomics' ability to decrease the cost of screening the validity of a drug, thus bringing drugs with a better potential for success to the costly clinical trial phase.<sup>3</sup> Furthermore, by targeting a specific protein which is known to cause

the disease, less time will be spent on drug discovery. Thus, the overall time spent and costs associated with R&D will go down. Nevertheless, the nature of patents and their advent since genomics is another area which will greatly affect the pharmaceutical industry and drug production of the future.

### ***Patents and its Affects on Pharmaceuticals***

Patents and the idea of intellectual property continue to maintain a central role within the research community. In academia and the research side of industry, the protection of one's innovations and the possibility for profit are key incentives to scientists. Due to the protection conferred by patents which "prevents others from capitalizing on the inventor's ingenuity and investment,"<sup>5</sup> patents grant the inventor an opportunity to develop their innovations more thoroughly. In terms of drug development, gaining patents for merely 20 years during which time clinical trials and approval by the F.D.A. must be performed, has caused drug companies to alter their drug development approach. In the 1990s the patent's period of actual usefulness was approximately 10 years.<sup>2</sup> This large decrease causes an even clearer sense of competition amongst companies. The actual patent process itself includes an application and a review by the United States Patent and Trademark Office (USPTO).<sup>5</sup> However, certain regulations such as the Patent Act of 1952, have given more clear cut authority, with Congress establishing criteria for the definition of a patent and methods for obtaining one. According to these specifications, a patent is any process, machine, manufacture, or composition of matter which falls under the requirements of utility, novelty, non-

obviousness, and description.<sup>5</sup> This means specifically that the invention must be novel and be useful in the real world.<sup>5</sup>

Within these limits one can place a multitude of things, but few share the controversial nature of genes. Thus, several key questions come into play. Can patents be obtained for genes? How does one draw the line? Do industries actually possess genes? With the emergence of genomics in the past decade all these issues have caused tension, as individuals see “owning” genes as amoral. However, the legal precedence for such issues has already been established, making the issue even more complex. Since the United States Supreme Court’s decision in 1980 on the *Diamond v. Chakrabarty* case, patents can be issued to bacteria which have been genetically engineered.<sup>5,11</sup> Patents however have an additional impact on the pharmaceutical industry. In order to extend their exclusivity to drugs and thus, postpone its release as generic, pharmaceuticals do two things. First, they attempt to change the drugs slightly, making them eligible for another patent. Second, new uses for the drugs are found, for example in combination with other drugs so the patent can be extended, extending the patent for three more years.<sup>1</sup> This method allows pharmaceuticals to maintain their rights while attempting to develop other drugs.

### ***Genomics affects on Pharmaceuticals and Patents: The Crossroads***

After the completion of the Human Genome Project in 2003 new horizons have been revealed to scientists. In particular, the discoveries have and will continue to influence the future of the pharmaceutical industry and patent policy. Thus, these three topics have had a big impact on one another. The magnitude of the affect can be seen by

the fact that in 2000 alone more than 25,000 DNA-based patents were issued falling under several different categories of methods and research.<sup>8</sup> Biotechnology has forced the Patent Act to become more focused. Uniqueness and utility have now become the focus of the act, while Title 35 has been expanded to emphasize the importance of allowing the “purposeful human intervention” to meet the uniqueness standard.<sup>5,11</sup> However, the nature of the issue remains more complicated in terms of gene patents, which come into the spotlight with the advent of genomics. Due to the moral issues mentioned earlier, gene patents have become somewhat analogous to the stem cell issue.

Thus, the key question has become, what are the limits to gene patenting? In 1999 the USPTO created the Revised Interim Utility Examination Guidelines which presented the idea that a single-nucleotide polymorphism (SNP) or an expressed sequence tag (EST) can be granted a patent if it has a clear function.<sup>7</sup> Nevertheless, there still remains quite a bit of grey-area since the term “well-defined” has a vague connotation. It is for this reason that more limitations and definitions need to be put in place to eliminate this grey area. In particular, three areas have been mentioned as needing clarification. First, the idea that automatic gene sequencing can be considered as an invention or discovery blurs the understanding of patents in the age of computers. Second, some believe that SNP and/or EST should only be patentable if they give incentive to companies to create new drugs. Finally, and perhaps the biggest issue is whether a piece of information or law of nature can be patented, questioning the identity of an invention.<sup>7</sup> Thus, it has been suggested that revising these policies can be done by encouraging “basic research patent pools,” which will accumulate several patents into one, ultimately allowing researchers to use all the patents for a licensing fee<sup>10</sup>. In this way, legal issues concerning intellectual

property rights would do less to hamper development. With the greater integration of genomics, the issue of whether gene sequences are considered information complicates things. Nevertheless, the trend has been to grant patents to genes that can diagnose and cause specific diseases.

From the point of view of the pharmaceutical companies; however, the principals of genomics have also had many affects on the industry. With the sequencing of genomes, the possibilities seem to be endless. In the human genome there appear to be more than 1.4 million single-nucleotide polymorphisms and more than 60,000 of these code for genes.<sup>6</sup> Slowly all of these areas are being tested or have been tested to see if they have a response to medications and can be used as target genes. However, this process is difficult since several proteins and genes work together and ultimately affect the drug's usefulness. This complexity slightly hampers the industry's view of genomics as increasing efficiency in drug discovery, but only slightly. Furthermore, the specificity of the drugs produced through genomics causes some to believe that pharmaceuticals will only invest if they can be guaranteed exclusive rights to the sequences associated with the drugs<sup>7</sup>. Throughout all this one thing is clear, the potential of the technology is enormous, as medications specific to each individual would be produced. But this still raises the questions of what effect this would have on the industry. Would it be as profitable? Unfortunately, these questions do not have solid answers. Nevertheless, genomics will quickly create answers these questions as it creates a new direction for the pharmaceutical industry.

Genomics has created new tools for understanding health and disease, thus leading to the advent of pharmacogenomics. This new field specifically targets the

individualized treatments developed through genomics. Thus, pharmacogenomics refers to all the genes which affect how drugs interact with the human body.<sup>9</sup> In particular, new emphasis is placed on new technologies which elucidate the differences between DNA sequences. These differences are important because they aid in drug development by allowing researchers to find and target disease development pathways. Also, these differences will be used to create medications for the individuals genetically predisposed to these diseases.<sup>9</sup> Thus, the industry will shift from looking at the larger market to targeting subpopulations. Populations will soon be defined by their genetic make-up. In addition drug development will become more targeted, as drugs will no longer need to help and be safe for the whole population. Instead, the drugs produced will be a “sure thing” since they will focus on a specific group. There is still a debate among the pharmaceutical industry however, because this change will cause a complete shift in marketing. Nevertheless, ultimately, molecular technology will allow the targeting of medications and dosages that will be optimal for patients<sup>9</sup> and perhaps lower the costs associated with clinical trials. Thus genomics has established a new horizon for this lucrative industry.

### ***Conclusion***

With the advent and boom of the biotechnology industry a new horizon for patent policy and pharmaceuticals has become present. In particular, the area of genomics and the possibilities created through the new knowledge of genes has forced an upheaval of the industries and policies formerly in place. As far as both patent policy and pharmaceuticals are concerned, the future looks much different with the advent of



genetically influenced treatments. Nevertheless, the hopeful notion of finding treatments that are specific to individuals and the decrease in risks is enough incentive for change. The adjustment of past policies and the steps taken to regulate the industry, however are still in the process of change. Until this is done the full extent to which new effective drug treatments will be available to patients will be held at a stand still. When the limitations are resolved, however, the bright future on the horizon will become reality.

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