
Biotech Changes the face of the Legal Profession

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The profound changes resulting from groundbreaking scientific advances and the biotechnology companies built upon them are so easy for us all to see. We see results in the drugs that we take, the medical treatments available, the investments in more and greater research by our leading universities and companies large and small.

In the legal profession, we too have seen changes, and the face of law practice has forever been changed.

The forces that led to these profound changes in law practice gathered strength over many years. There were the significant scientific developments in the life sciences, and the recognition in the venture capital community that such advances could be the foundation for great and

important businesses. Organization of the businesses, of course, required lawyers. But the real seeds of change for lawyers were sown by three factors.

First, the biotechnology community recognized that, given the magnitude of the investments required to bring a product to market, it would be critical to obtain and protect intellectual property -- specifically, patent protection. Without patent protection progress in the community and the constant influx of new ideas into the world, innovation would be severely diminished.

Second, in 1980 the Supreme Court decided in *Diamond v. Chakrabarty* that patent protection would in fact be granted for live, human-made micro-organisms.

Before this decision, the issue of whether genetically engineered organisms would even be patentable was unanswered. With this decision, the Supreme Court unequivocally held that there could be real and meaningful patent protection in the life sciences.

Third, the Court of Appeals for the Federal Circuit was created to have exclusive jurisdiction over appeals from the trial courts of all patent cases, and it was widely viewed as patent friendly.

The Federal Circuit issued a series of decisions strengthening the value of patents, including those in the life sciences.

The forces combined in a case tried here in Boston in 1989 that made it clear to all just how important lawyers can be to the biotechnology industry. The case was *Amgen v. Genetics Institute*. It involved the now wildly successful and sometimes controversial product erythropoietin (EPO). This was a

seemingly endless war for patent rights to EPO, a hormone regulating red blood cell production. The case involved the application of virtually every patent principle to this new and emerging field. It was acknowledged to be the first major biotechnology trial in the country. The four-month trial to a packed courtroom and the almost breathless anticipation for the court's decision marked a turning point. The importance of biotechnology and the importance of lawyers to the protection of the investments scientists and businesses were making were as clear as possibly could be.

Nearly 20 years later, law practice nationally and in Boston in particular has been changed permanently. Today, my firm, WilmerHale, has over 1,100 lawyers on three continents. More than 150 of those lawyers have undergraduate or advanced degrees in the sciences or technology. Almost every deal, every license, every joint venture and every litigation in the life sciences requires the training and ability to understand the sophisticated concepts involved. And, many other firms have developed similar expertise to meet the same needs.

For lawyers and law firms working with the biotechnology industry, there is no turning the clock back. We will need to continue to recruit not only the best lawyers but some of the best scientist-lawyers.

We will need to be lawyers who can understand, translate and communicate in complicated scientific fields. We will need to be lawyers who can work side by side with the best scientific minds in the world. Those who adapt to this new legal environment will succeed and those who do not will be left behind.

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Genetic Institute in the Amgen v. Genetic Institute case discussed in this article

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