

Biotechnology Commercialization Failure

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Abstract

The biotechnology industry is the most research and development intensive and capital-focused industry in the world. The biotechnology industry relies on the protections afforded by the patent laws and on the opportunity to exclusively license discoveries from academic partners through the mechanisms established in the Bayh-Dole Act (Schurman, 2003).

Commercialization

Commercialization requires applied research, business strategy, marketing, product support and other variables that are not in mandate of university or federal government and therefore best carried out by the private sector. Failure to commercialize can result from any or several of the above-mentioned variables. Patents also play a significant role in investment of capital in the biotechnology markets. Investors measure opportunities in the biopharmaceutical and pharmaceutical sector through potential sales of drug/product, the market exclusivity prospect through patent, marketing exclusivity, orphan drug exclusivity or other means and strength and predictability of patent protection (Schacter, 1999).

Case Study

The intrinsic risks and uncertainty of the R&D process have left a majority of pharmaceutical companies with gaps in their portfolios as late-stage products fail. FORMER stock market listing British Biotech suffered yet another indignity, admitting its most promising drug will never come to market. It abandoned trials of its anticancer treatment marimastat after patients treated with the drug reacted no better than those

receiving a placebo. Marimastat was rejected for lack of efficacy in phase III (Fred et al 1998).

The Marimastat saga began in December 1995, when there was an announcement relating to Marimastat. One comment was that it brings to light a glimmer of hope for millions of cancer sufferers. Although caution was advised, one article nevertheless stated that British Biotech, responsible for developing the drug, had reported evidence that initial findings are showing positive results. At the time it was expected that Marimastat, an oral matrix metalloproteinase inhibitor (MMPI), would most likely be released in 1999 and experts say Marimastat could prove to be a breakthrough in the fight against cancer (Fred et al 1998).

Companies may therefore be forced to market products emerging from internal R&D that do not fit their planned therapeutic strategies. This can result in a diverse, disparate marketed portfolio. Attention is diverted away from main franchise areas of the company; sales forces have to be retrained and new customers understood (Schurman, 2003).

Conclusion

Biotechnology falls between the two extremes. It is easiest to object to new biotechnology if it yields a botched clinical trial or a deadly allergic reaction to a genetically modified food. But the real threat of biotechnology is far more subtle and harder to weigh in any utilitarian calculus. Biotechnology offers the potential to change human nature and therefore the way that we think of ourselves as a species (Schurman, 2003).

Bibliography

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