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Genetically engineered oil-eating microbes for bioremediation: Prospects and regulatory challenges

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A B S T R A C T

The use of genetic engineering to enhance the natural capacity of microorganisms for remediation has become very promising with new scientific discoveries occurring every year. Unfortunately, the application and commercialization of this technology has not kept pace with these research discoveries. This article uses two examples of genetically engineered microorganisms that were designed but never deployed in the clean-up of wastes to show how the application of genetically engineered microbes for bioremediation has not progressed in line with other biotechnological innovations. We argue that a more risk-based regulatory environment that fosters commercialization is important. In addition, we show how scientists could foster the commercialization of genetically engineered microbes for bioremediation through the use of technical safeguards and the consideration of regulatory challenges at the onset of their research. The lessons provided by these challenges could be applicable to current biotechnological innovations that face similar regulatory challenges.

1. Introduction

Bioremediation is one of the "Top 10 Biotechnologies to Improve Global Health" [4]. Large amounts of toxic chemicals are released into the environment, either deliberately as in the application of pesticides, or accidentally as in the case of oil spills. A variety of microorganisms capable of efficiently degrading toxic compounds and xenobiotics in the environment have either been isolated or engineered. However, the actual application of such microorganisms in bioremediation has not progressed with the same momentum as their invention, or as other innovations in the biotechnology arena.

Microbial bioremediation is defined as the process by which microorganisms like bacteria degrade or transform hazardous organic compounds into non-toxic substances. Such hazardous compounds include benzene, toluene, PCBs, dioxins, and nitro-aromatics. There have been major advances in the research and design of genetically engineered microbes for bioremediation [12,5,17] and many bioremediating microorganisms have been isolated.

Since naturally occurring microorganisms are not capable of degrading all toxic chemicals, especially xenobiotics, genetically engineered microorganisms have been tendered as the *sine qua non* for bioremediation, and genetic manipulation has advanced. However, there have been very few field trials for the use of genetically engineered microorganisms for bioremediation [14].

Although there has been a boom in the commercialization of genetically modified drugs, crops, and other biotechnological innovations over the last two decades, genetically engineered microbes for bioremediation have not been commercialized [14,18]. Some have speculated that cost, complexity, and a burdensome regulation may be a reason for the lack of commercialization [18]. However, that explanation does not seem to present the full picture. Since the United States Environmental Protection Agency (EPA) started regulating genetically engineered microbes

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about 30 years ago, there has been no commercialization of any genetically engineered microbe for bioremediation, except in demonstration projects in closed reactor systems [18,16].

What happened to the promise of genetically modified microorganisms for bioremediation? We present an analyses of the research-commercialization gap using examples. We evaluate this gap from both a regulation and research-based perspective, taking into account the containment technologies that have been developed. In this study, we reviewed recent literature on the development of genetically engineered microbes for bioremediation and interviewed Ananda Chakrabarty, the first scientist to patent a living organism (the "oil-eating microbe"). Through our analysis of the interview and literature review, we found that the inability of scientists to adapt their research to the prevailing regulatory environment, lack of a risk-based and evolving regulatory framework, and inadequate support by government agencies to help bioremediation researchers bring their products to the market could be an explanation for this gap.

We suggest that risk-based regulation and the design of genetically engineered microbes with technical safeguards could bring about the important translation of this kind of bioremediation research from the lab to the field, where it is most needed.

2. The potential of a genetically engineered microbe for bioremediation

During the 1980s and 90s, there was a spark in research in the development of genetically engineered microorganisms for bioremediation [20]. The era held promise: many bioremediation companies were born and researchers in genetic engineering and microbiology increased the intensity of their research in this new and emerging field [3]. However, due to the regulatory hurdles and high technical cost required to satisfy regulation, many of these companies went out of business and experiments on genetically engineered microorganisms were confined to research institutions. The research moved from the agenda of companies to those of academies.

The first genetically engineered microbe was created by an Indian-born microbiologist and genetic engineer, Ananda Chakrabarty, in 1971 [15]. The patent was approved in 1980 by the United States Supreme Court. The microbe was a variant of the genus *Pseudomonas* and was capable of breaking down the constituents of crude oil.

Chakrabarty showed that four strains of the common *Pseudomonas* bacteria contained enzymes that enabled them to break down different hydrocarbons. He first determined that the genes for oil-degrading enzymes were carried not on the microorganism's chromosome, but rather on other extra-chromosomal elements known as plasmids. He combined these plasmids into a strain of *Pseudomonas*.

Unfortunately, due to regulations and public concerns of using the microbe for bioremediation, Chakrabarty's breakthrough microbe still sits on a shelf, unused. At the time, the new superbug created by Chakrabarty was said to have the potential to degrade oil 10–100 times faster than other non-genetically engineered independent strains [15].

This oil-eating microbe created by Chakrabarty is not an isolated example; there are other cases of genetically engineered microorganisms that have been designed but not applied in bioremediation [12,7,19]. For example, a bacterium, *Deinococcus radiodurans*, which is the most radiation-resistant organism known, was successfully engineered to degrade toluene. However, it has not been applied or commercialized for bioremediation [9]. Several factors may be associated with the failure of advancement from research to commercialization.

3. The regulatory challenge of genetically engineered microbes for bioremediation

The regulatory environment plays a central role in either advancing or stifling the application of novel biotechnological inventions. On the heels of the oil-eating microbe created by Chakrabarty companies who desired to commercialize genetically engineered microorganisms in the 1980s and 90s were decelerated by the regulatory framework in the United States [20]. The regulatory hurdles were partly premised on the inadequacy of biotechnological inventions to thoroughly contain genetically modified bacteria once released into the environment.

For example, a genetically engineered microbe was created to effectively degrade Agent Orange[1], a toxic defoliant used by the United States military during the Vietnam War. The engineered microbe was produced from a strain of *Burkholderia cepacia* and was designed for the removal of Agent Orange at the U.S. Air Force in Pensacola, Florida, where it was stored prior to its shipment to Vietnam. Agent Orange has been linked to increased cancer cases [10,1]. According to Charkrabarty, the research on the Agent Orange-degrading microbe was partly funded by National Institute of Health and partly by the EPA, the EPA was reluctant to approve its use based on concerns regarding its potential impact on the environment. The EPA wanted assurance that the toxic chemical-degradative genes would not be transferred by natural gene exchange mechanisms to neighboring pathogenic bacteria, and that such pathogenic bacteria would not be able to feed on the pollutant. According to Charkrabarty, "These are tricky issues to be resolved through laboratory experimentations and require massive field trials in isolated sites."

The EPA has the authority to regulate the release of genetically engineered microorganisms under Section 5 of the Toxic Substance Control Act (TSCA). Manufacturers of genetically engineered microbes are required to submit a Microbial Commercial Activity Notice (MCAN), which states *inter alia* the environmental fate, health effects data, and physical and chemical properties of the proposed modified microorganism. Genetic modification of microorganisms is presumed as high risk in the regulatory framework of the EPA [16]. However, given the application of genetic engineering in the pharmaceutical and agricultural sectors, mere genetic manipulation should not necessarily be considered high risk but should be dependent on the

[1] 1:1 mixture of two phenoxy herbicides, 2,4-dichlorophenoxyacetic acid (2,4-D) and 2,4,5-trichlorophenoxyacetic acid (2,4,5-T).