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Fungus that once stonewashed jeans now offers promise in biotech

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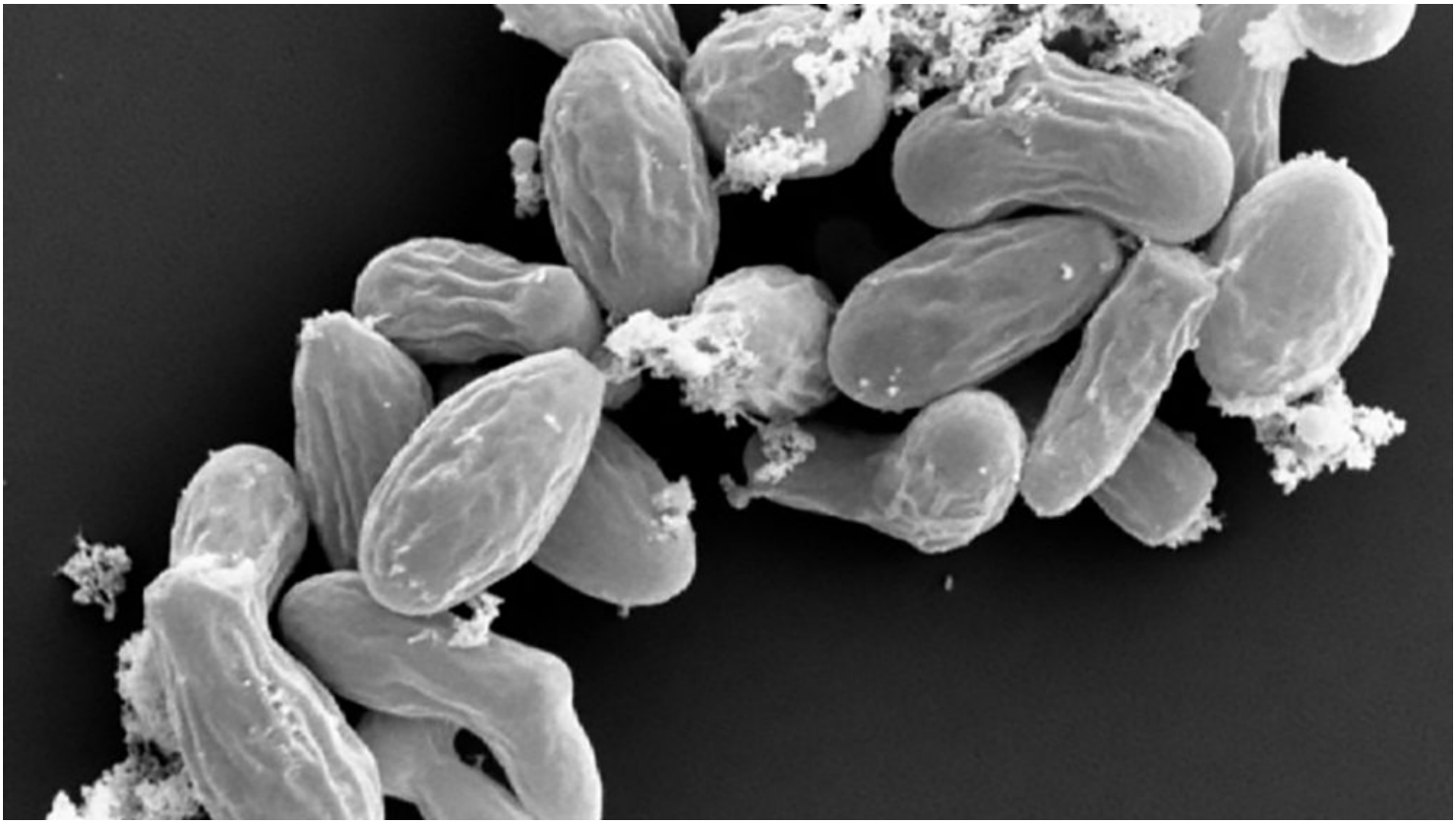

Myceliopthora thermophila. *Dyadic International Inc*.

Mark Emalfarb is a big fan of fungus. "There's a fungus among us," he says often.

Emalfarb, who grew up working in his family's landscape stone business, had his first success 30 years ago, importing pumice from the Soviet Union to "stonewash" blue jeans. But the industry was moving away from stones — which clogged washing machines — to enzymes that produced the same effect.

Using his Russian connections, Emalfarb hired some local scientists who discovered that the fungus Myceliopthora thermophila could give jeans that stone-washed look for one-third of the price of the enzymes. That became his second successful business venture.

Then, about a decade ago, he recognized that the same fungus could be used to efficiently break down cornhusks and other biological material into biofuels. He sold that business to DuPont for $75 million.

Now, Emalfarb is using M. thermophila to produce the proteins needed to make biologic drugs.

"We're aiming now at the final frontier," he said, citing the famous quote from Star Trek. His company, Dyadic International[1] of Jupiter, Fla., intends, he said, to "change the game in the way biologic vaccines

and drugs are made. We want to make them at a fraction of the price they're made today."

These proteins are currently manufactured by a line of Chinese hamster ovary (CHO) cells. Emalfarb, Dyadic's president and CEO, said his fungus, which the company has nicknamed C1, can make five to10 times more protein in half the time of the CHOs. "It's not 3 percent marginally better," he said.

Dyadic still needs to win approval from the Food and Drug Administration before it can use the fungus in drug manufacturing.

Making medicines in the cells of simple organisms isn't new. Since the 1980s, the insulin that some peoples with diabetes depend on can be produced in bacteria and yeast, for example, thanks to recombinant DNA technology.

Chinese hamster ovary cells may sound like a weird or gross production system, but they work well in the making of monoclonal antibodies, they're safety is proven, and the industry understands them. Even a system that works better will have a hard time being accepted, because of that comfort level, said Sir Gregory Winter, a British biochemist and pioneer of therapeutic monoclonal antibodies, who is now involved in his own startup, Bicycle Therapeutics[2].

Any new technology "has to offer something really important you can't do otherwise," beyond simply a lower price, said Winter, who wasn't familiar with Dyadic's work. Greater efficiency is terrific, he added, but "is that going to be enough to overturn the technology if it means you've go to re-educate an entire field of process engineers?"

Emalfarb isn't deterred. Attending the annual Protein Engineering Summit[3] in Boston last week, he seemed energized by other people's ideas for "CHO stoppers."

Nor is he deterred by the possibility of competition to replace Chinese hamster ovary cells. "We think we have the triple-crown-winning thoroughbred versus the three-legged donkey," he said in a phone interview before the conference, where Dyadic was giving a presentation Thursday.

Because of several fortuitous accidents, Emalfarb says C1 can also produce a much purer drug than the Chinese hamster ovary cells can, requiring less need for purification.

Because it's so efficient, C1 can make the same amount of drug in a 2,000-liter bioreactor as is currently made in a 20,000-liter one, Emalfarb said, tapping into the industry trend toward smaller, more nimble production lines.

For 30 years, from rocks to blue jeans to biofuels to medications, Emalfarb said he's helped luck along by hiring top-quality researchers to compensate for his own ignorance. "We knew we knew nothing, so we found someone who did."

For instance, twice in the late 2000s, he hired Bruce Pascal, now director of bioinformatics at the Scripps Research Institute in Florida, to analyze the genetics of M. thermophila for Dyadic, looking for other useful proteins its genes might produce. Pascal said he does this kind of analysis for a company maybe

once every five years. “It’s not a sure-fire method but it can certainly give you some strong clues,” he said. “I just provide the data and they can make their own conclusions.”

That genetic information allowed Dyadic to maximize the yield from M. thermophila, and convince DuPont to buy the company. Now, it’s allowing Emalfarb to dream that he can help solve the problem of skyrocketing drug prices, and enable more people access to life-altering medications.

“All from a Russian fungus among us that started out washing blue jeans,” he said.

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