

Innovation and Entrepreneurship

Business Success in the Biotechnology Era

All products have a life cycle, and success in any business requires recognition of when a product's life is near the end. When that time comes, new products must be added to ensure the business will survive. Identification of a new product or technology requires a continuous scanning of the discovery pipeline for opportunities. However, the identification of a discovery destined to become a "blockbuster" may not be easy. Product life cycles are especially important for dental manufacturing companies because their product line is usually limited and targeted to a narrow customer base. So what is the best method for scanning for new discoveries and identifying potential blockbusters? Surprisingly, using your eyes and ears remains the best advice.

In 1843, while watching a demonstration of nitrous oxide as "laughing gas" in an amusement park, the Hartford dentist Horace Wells immediately appreciated the anesthetic properties of the gas and became the first person to extract teeth using it. Only a few years later, in 1848, another dentist, William Morton, after listening to a chemist lecture on ether, realized it could induce unconsciousness. Using ether as an anesthetic, he removed a tumor from a patient's jaw.¹ In 1895, you might have read a news report stating the German physicist Wilhelm Roentgen had discovered x-rays and realized the diagnostic implications for dentistry.¹ Finally, Frederick McKay recognized

that patients with few (if any) caries had brown staining on their teeth.² His conclusion that fluoride in the public water supply (describing fluorosis for the first time) stained their teeth and prevented caries was a "blockbuster." These observations are true blockbusters in that they acted as platforms on which new industries were built; the products manufactured by these industries have continued to remain profitable for more than 100 years and show no signs of coming to the end of their life cycle.

Blockbusters that Displace Existing Industries

It wasn't long before these discoveries—x-rays, anesthesia, and fluoride—emerged as products. In fact, these discoveries were used immediately because no alternatives existed. No other ways to see bones, eliminate pain, or prevent dental decay had been discovered, so no products on the market could compete with x-rays, ether, and fluoride; no existing industries were displaced. But let's consider another type of "discovery"—one that is just as much a blockbuster but results in the displacement of an entire industry.

Suppose it is 1900 and you are the owner of a company making buggy whips. Your buggy whips are recognized as the best on the market and are sold worldwide. It's the beginning of the 20th century; the US population is growing and with it the demand for transportation, as well as buggy whips. Business in 1901 is profitable with sales increasing each year. Fast-forward to 1908; on a bright sunny morning, while having breakfast, you read in your newspaper that someone named Henry Ford has announced the first of his Model T automobiles has just rolled off the assembly line.³

As CEO of the buggy whip company what will be your response? Will you recognize the life

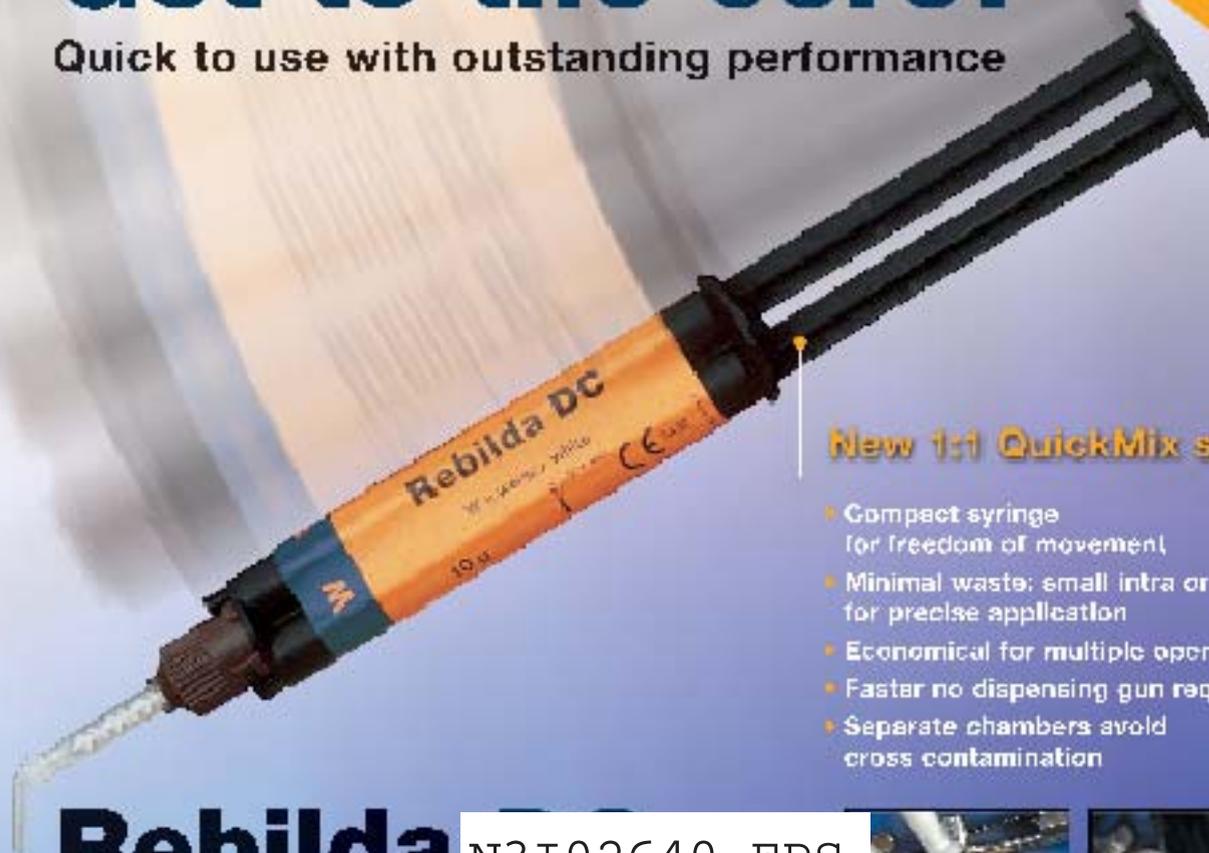


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What if:

- in 1908 your business made buggy whips?
- in 1975 your business made electric typewriters?

cycle of the buggy whip business is about to come to an end and the entire industry will become obsolete? If you anticipate this event's impact on the transportation industry and meet with your senior managers, what type of plan will you develop in response?

Obviously, the example of the automobile's impact on the buggy whip industry is far from an isolated example. Let's fast-forward again and look at an event, the effect of which, as a displaced blockbuster, might have been somewhat more difficult to predict. It is 1975 and this time you are the CEO of a company that manufactures electric typewriters. Again, business is going well. Typewriter technology has improved steadily since its manufacture by E Remington of Iliou, New York in 1874. In its first year the company sold about 400 machines for \$125 each.³ Again, it's a bright sunny morning in the mid-1970s, and as you enjoy your breakfast, you read in the newspaper that 2 young men, William Gates and Paul Allen, have

formed a partnership to make something called software for the developing personal computer industry. As the CEO of a typewriter company what would be your response? Would you recognize the impact of this emerging technology on your own business? Would you immediately call a meeting of your senior management, and what plan would you develop in response?

Clearly, with discoveries like the Model T and the personal computer, the response of the CEO of the industries destined to be displaced is critical. If the CEO of the buggy-whip company immediately met with Henry Ford and set up a dealership, the outcome might have been different. With Gates and Allen, I'm not sure what the CEO of the electric typewriter company could have done. To buy stock in Microsoft would have been the best bet.



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Credibility

Scientific Expertise:

Is your source reliable?

Prestige:

Is your source trustworthy?

Figure 1—Credibility requires access to dental-school-based scientific expertise to ensure product evaluation is reliable and performed according to rigorous academic standards.

Sequencing of the Human Genome

Again fast-forward. It is 2002 and you are the CEO of a dental manufacturing company. On CNN you learn the human genome has been sequenced. The announcement was jointly made by 2 groups: the first federal, headed by Francis Collins, Director of the National Institute of Genomic Research, and the other private, headed by Craig Venter, President and CEO of Celera Genomics.⁴ As you listen to the announcement, you may understand this is a blockbuster discovery and immediately call a meeting of your senior managers. The questions on the agenda would be: Is this a discovery with the potential to displace our business and our industry? If so, how should our company respond to this blockbuster?

Assumptions of Clinical Dental Practice Include:

- Environmental agents—especially microbes—result in dental diseases (caries and periodontal disease).
 - Dental tissues (teeth and periodontal supporting structures) are incapable of regeneration.
-

The Need for a Response

Perhaps the CEO did not call this meeting. It is possible in certain dental companies the significance of this announcement on the dental profession was not understood and, therefore, not perceived as a threat to the business.

In my opinion, this discovery was the most important scientific development in the last 100 years for its potential impact on the dental industry because it challenges the 2 existing assumptions on which the dental profession is based. In a previous column⁵ in this series I have discussed these assumptions but because of their relevance I will review them below:

1. A unique agent or agents, usually microbes, when present in sufficient numbers and at the appropriate site, produce an infection resulting in caries and periodontal disease. This assumption leads to the logic that eliminating the microbe will cure the disease.

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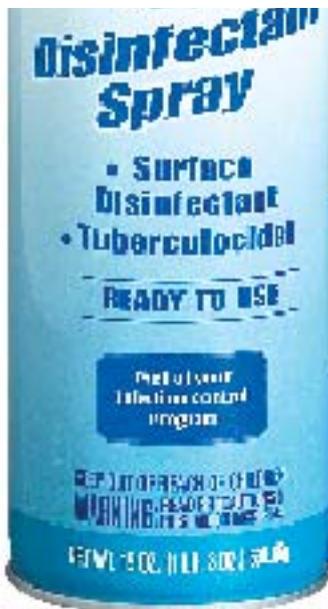
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Evidence-Based Decision Making

- Treatment protocols: Based on the results of scientific studies.
- How do we know which research results are reliable and applicable?
- Identify experience, timing, values, and leadership.
- Identify outbreaks, threats, and emerging issues

Figure 2—The dental profession is shifting from an experience-based discipline to one that is evidence-based. This shift has been well received by the public.

Scanning the Landscape for Potential Blockbusters: A Role for Dental Schools and Dental Industry Associations

- Opportunities to attend seminars on biotechnology
- Access to faculty with expertise in biotechnology
 - Opportunity to have products evaluated using rigorous scientific standards
- Presentation of new products and technologies in various stages of development ranging from early discovery to final product

Figure 3—Dental schools can provide a valuable service in identifying potential blockbuster discoveries.

2. The second assumption derives from the requirement for a functional dentition to sustain good health and even life. This means the dentist's responsibility for patient care does not end with elimination of the infection. In fact, the process of removing the diseased tooth structure or, in the case of periodontal disease, the destruction of bone produces the next phase of treatment—the restoration of tooth structure with a filling material, the fabrication of a prosthesis or placement of an implant, or periodontal surgery, including bone and tissue grafting. These forms of treatment are necessary because dental tissues (ie, dentin, enamel, and bone) are incapable of regeneration and repair, and humans have only 2 sets of teeth. To repair the destroyed part of the tooth, a restorative material is needed, and when a tooth or teeth are removed, they are replaced with prosthesis—a partial or full denture. Imagine how different the restorative phase of a dental practice would be if enamel and dentin, like the liver, were capable of regeneration or if we, like sharks, had an unlimited supply of teeth?

The sequencing of the human genome has the potential to change dental practice by invalidating these assumptions. For caries, the therapy may shift from a mechanically based therapy of removing plaque by scraping and polishing to a biochemically based therapy of removing plaque with pharmaceutical agents. Another possible treatment would dis-

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place the “infectious” bacteria with those genetically modified to eliminate their infectious potential—a process referred to as “competitive infection.”

Similarly for periodontal disease, although the microbe will remain as an initiator of the disease, genetic information provided by the human genome sequence will allow for the development of diagnostics for the disease. The first signs of using genomic information for testing have emerged with the introduction by Roche Diagnostics of a genetic test (AmpliChip™ CYP450^a) that predicts how an individual will react to drugs and dosages. The test uses a “chip” that may potentially be customized to include genetic susceptibility to periodontal disease.

In the case of the Roche test kit, the AmpliChip™ CYP450 is a wafer-like material coated with DNA chip (GeneChip®^b) manufactured by AFFYMETRIX®. These chips have been under development for some time, but they have only recently come to the commercial market. Their capabilities are of interest to all in the health field, including the oral health field. In brief, using a patient’s DNA, this test will help determine a patient’s unique response to chemical substances. The Roche kit currently tests for individual responses to drugs. However, you could possibly have AFFYMETRIX® make a chip for your company. What might a forward thinking dental company wish to test?

Scanning the Landscape for Potential Blockbusters: The Importance of Credibility

Given the importance of a company’s reputation when selling a product, when a dental company is considering a new biotechnology-based product or acquisition of a biotechnology company, it should evaluate the results of the scientific studies on the latter company’s product. Clearly, a little dose of science can go a long way to protecting the credibility of the dental company when considering acquisition (Figure 1). Moreover, regardless of whether the dental company sells to dentists, the public, or a distributor, it has a reputation to protect.

Both the dental profession and the dental industry have humble beginnings. The first dental practices were set up in barbershops and saloons, and the dental industries’ initial products were tonics and toothache remedies sold from the back of a wagon. Both groups have come a long way since then. Today, the public expects dental practitioners and industries to act as professionals with codes of conduct and adherence to ethical standards, ensuring credibility of claims for therapies and products.

The dental profession currently is moving from an experience-based decision-making process to one that is more evidence-based; that is, treatment protocols are based increasingly on the results of scientific studies (Figure 2). This shift adds considerable credibility to statements made by the dental professional. The public has responded positively to this shift, and, not surprisingly, credibility has become critically important for the members of the dental industry as well.

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Table 1—The Center for Research and Education in Technology Evaluation (CRETE)

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CRETE promotes discovery, innovation, and the commercialization of new dental, oral, and craniofacial technologies and products.

CRETE provides resources to conduct research and development in technology evaluation.

CRETE can develop programs to introduce innovative technologies.

Table 2—The DMA/DTA Announces a New Forum “Selling Brand America”

WHERE: GREATER NEW YORK DENTAL MEETING

DATE: December 3, 2003

TIME: 2:00PM–4:30PM

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PRESENTERS: Innovators/inventors seeking premarket exposure for potential products.

For additional information on the forum “Selling Brand America,” contact Bernard W. Janicki, PhD at bwjanicki@hotmail.com

The importance of credibility was brought to the forefront recently in what I will call the case of the corked bat. Apparently, Sammy Sosa, one of baseball's all time greats, swung at a pitch and cracked his bat, revealing to the umpire a bat drilled out in the center and filled with cork. Batters apparently believe a cork-filled bat will allow them to swing faster and produce a springboard effect, thus driving the ball further. I feel for Sammy, not because he was caught, but because no such thing as evidence-based baseball exists. Were it so, Sammy would have been aware of experiments indicating a corked bat unequivocally does not help a hitter. Though the bat is lighter, allowing more time to swing, the introduction of the cork decreases the bat's mass, and the ball does not travel as far. He would also be aware that the insertion of cork makes the bat neither spongier nor act like a springboard. In fact, experiments have shown that the contact between the ball and bat is too brief—one thousandth of a second—for any springboard effect to be achieved.⁶

This lesson concerns *credibility*; when lost, it is difficult to regain. By availing himself of the results of scientific studies, Sammy Sosa could have avoided embarrassment and saved his reputation. Who can forget the response of Johnson and Johnson to the TYLENOL[®]c tampering episode and how the public responded to the Herculean effort the compa-

ny made to ensure the safety of the public? They protected the TYLENOL[®] brand name and the company credibility. (For additional comments about credibility and its importance to the dental industry please see my previous article.⁷)

Scanning the Landscape for Potential Blockbusters: A Role for Dental Schools in Creating Credibility

A developing biotechnology company might provide experimental results on a biotechnology product, but often the dental company might not have the expertise for its evaluation. In such cases, the company should reach out to experts, most often the faculty of university-affiliated dental schools. It is no accident that the industries congregate around academic centers. For example, many companies are located on Route 128 in Boston, the home of several universities, including Harvard and MIT, and some are located in Research Triangle Park, North Carolina, the home area of Duke University, North Carolina State University, and University of North Carolina.

Several dental companies have turned to dental schools, especially schools that have set up centers specifically for this purpose (Figure 3). One example is the University of Connecticut School of Dental Medicine and its Center for Research and Education in Technology Evaluation (CRETE). As listed in Table 1,

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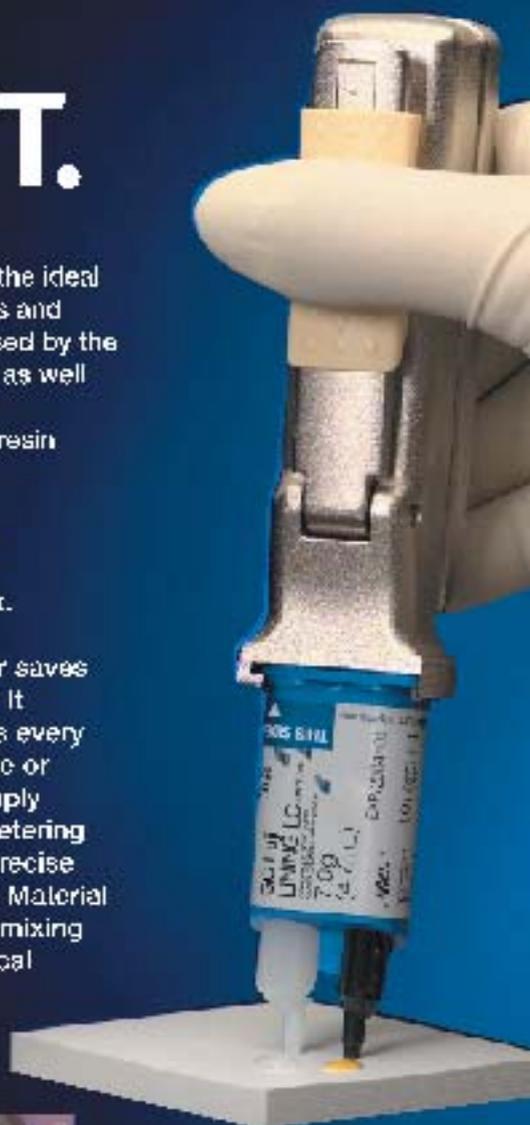
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CRETE provides the dental industry with opportunities to attend seminars on biotechnology, access faculty with expertise in biotechnology, and have products evaluated using rigorous scientific standards.

Scanning the Landscape for Potential Blockbusters: A Role for Dental Industry Associations

For information on biotechnology, dental companies can seek advice from dental industry associations. For example, for 3 years, the Dental Manufacturers of America (DMA) has cohosted the Entrepreneurial Venture Fair with the National Institute of Dental and Craniofacial Research. Held in 2000, 2001, and 2002, the fair provided attendees at its Chicago meetings with access to 51 inventors presenting new products and technologies in various stages of development, ranging from early discovery to final product.

To reach a broader audience for 2003, the DMA leadership is presenting innovations in a new format at the Greater New York Dental Meeting on December 3, from 2:00PM to 4:30PM. Titled "Selling Brand America," the program will allow presenters to describe new products to dentists, as well as to a greater range of potential buyers, including dental assistants, hygienists, and office managers. Table 2 provides a summary of information for the program. (For additional commentary about the advantages of an academic-industrial complex to the dental industry please see my previous column in this series.⁸)

Scanning the Landscape for Potential Blockbusters: The *CosmoGirl* Magazine Success Story

Although consulting the dental school faculty is one way to scan the landscape for a potential biotechnology blockbuster, the other way is to use your own eyes and ears. I suggest concentrating on the teenage generation. For example, consider the following as reported in *The New York Times*.⁹ For decades *Seventeen* magazine has been the bible for young women—teaching and preaching style, manners, and makeup. But recently the new publication *CosmoGirl* has threatened that leadership position with readership doubling in the 4 years since its founding. Its message is empowerment, a message today's pre-teens can relate to and, it would appear, want to hear about. According to *The New York Times*,

Hearst Magazines announced the editor of *CosmoGirl*, Atoosa Rubenstein, was selected as the new editor for *Seventeen*. *The New York Times*, quoting Ms. Rubenstein, wrote she would continue with celebrities, fashion, and beauty, but the message of girl power would be the focus. *The New York Times* notes that today's 15-year-old has a cell phone and disposable income. She is growing up faster than previous generations.

Those of us in academia and industry, especially the dental industry, should read this newspaper article and take the comments of Ms. Rubenstein seriously. Perhaps this article is like many of those that appeared in the past and requires a meeting of your company's strategic planning committee. As a professor at a dental school, I realize this article will have an impact on me; some of today's *CosmoGirl* readers will be in dental school and my students. I know I will have to change how I teach. The question is: Will your company have to change how and what it sells to the empowered new generation?

Acknowledgments

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Columnist's Note: Thank you to those who contacted me about Biodontics and about the next Entrepreneurial Venture Fair. Your comments are always welcome especially those requesting information about entrepreneurship and innovation.



Syringes shown actual size

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Case courtesy of Dr. Robert A. Usher, Denton, TX