A hierarchical framework of new products development: An example from biotechnology

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A hierarchical framework of new products development: an example from biotechnology

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Keywords

New product development, Hierarchy, Biotechnology, Economic conditions

Abstract

Many new products are based on new technologies, which may in turn be based on new scientific discoveries. The extant literature on new product development has focused on how a firm may successfully commercialize new products. There is a corporate cost associated with new product failure, which extends beyond the final product-manufacturing corporation to all the parties involved in the supply chain for the failed product. The new product development community has developed frameworks for managing the new product development process to minimize new product failure, notably by incorporating customer preferences into a cross-functional approach to new product design and by creating a set of decision points or stage gates. The focus of these has been on the latter stages of the new product development process. Besides corporate decisions, society and its various institutions play a role in the shaping of new products from knowledge discoveries. Identifies how other participants may indeed influence the development of new products. Permits a more deliberate understanding of the possible impact of aiding or preventing a movement up the development hierarchy and so a clearer understanding of the potential benefits and opportunity costs may arise.

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Introduction

New products serve as an important part of economies. They drive the long-term growth of organizations, and so the long-term economic welfare of societies. Organizational growth leads to higher levels of employment. For example, a recent report from the US Senate's Joint Economic Committee's biotechnology summit (1999) states that "In 1998, the industry generated revenues of about $19 billion, spent $10 billion on R&D, and employed about 150,000 highly-skilled workers. Most biotech companies are fairly small, with two-thirds of firms having fewer than 135 employees." The market value of corporations is based, to a considerable extent, on their expected growth in earnings. There is a limit to the number and newness of new products that may be developed from existing technologies. The development of new technologies provides a fresh source of growth. So individual corporations are driven to manage growth both from existing products and also by investing in the development of new products. Further, society places a high value on entrepreneurs who build new technologies into products that in turn increase economic welfare and social capital. Not all new products succeed. Some because they do not meet market needs at the price that the market is willing to pay for them, others because of poor planning and execution leading to a mismatch between when and where customers would buy a product and when and where it is made available. In other words, due to management issues. Other products may fail as they are perceived as being detrimental to the environment or to and by a sufficiently large group of people. One of the potentially important new technologies that have emerged recently is genetic engineering that allows the development of a variety of new products, including genetically modified organisms (GMOs). There is considerable controversy about whether products based on this technology should even be allowed to exist in the marketplace, let alone allowed to succeed. And then there are new products that have failed even before they have been conceived either because they have not been thought of, deemed feasible, or because their components were killed even earlier.

New products do not just contribute to economic wellbeing. They often make a real

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difference in our quality of life. For example, again quoting from the US Senate's Joint Committee report (1999): "The biotechnology industry offers immense potential for cures to many diseases as it takes advantage of rapid gains in scientists' understanding of human genomics. About 80 biotechnology drugs and vaccines are already on the market and have helped millions of patients. Hundreds of additional products are being researched, or are currently in clinical trials. Biotech medicines approved for use include products to treat anemia, cystic fibrosis, hemophilia, cancer, and other diseases. In agriculture, biotechnology research is leading to greater yields of higher quality crops at lower costs." Since the successful new products are so important for our wellbeing, it is therefore important for us to have a comprehensive picture of framework of the possible pathways between scientific knowledge and its development into new products.

Several issues have emerged as being of importance to scholars and practitioners in the area of new product management specifically, and asset management in general. The area of new product management has been focused on responding to the competitive pressures in the market from the pace of introduction of number of new products, and the higher capital requirements for the development of new products based on the newer technologies. Both of these factors require attention to time. The faster a new product is launched, the sooner it will garner revenue and, as future revenue flows are discounted, the earlier a product is launched, the higher will be its present value. With an increasing pace of new product introductions, it is also felt that products will become obsolete faster. Also, because of the complexity of many of the newer products, including GMO-based seeds, there is a feeling that the market can only bear a few variants of a product leading to the concentration of the industry (see Goldsmith, 2001), and to a winner-take-all mindset.

To combat the danger of being late firms focus on being faster at converting a product concept into a commercial product (or cycle time). The issues that have received most attention in the literature have been that of reducing the cycle time or the time to market for a new product and reducing the failure rate of new product introductions. Since new product success is dependent on the communication between and among many departments as well as other commercial partners, much of the focus has also been on studying cross-functional process management tools such as quality function deployment (QFD) and concurrent engineering (Griffin and Hauser, 1993; Hauser and Clausing, 1988) to lead to more successful new products. New product development is fraught with uncertainty. To ensure that new information is incorporated into decisions on investments on a new product under development, the development process has been broken up into stages. The various stages of new product introduction are opportunity identification, design and prototyping, testing, and product introduction. At each stage a go/no go decision is to be made based on the latest information. Cooper (1990, 1994) provides an elaborate study of the stage-gate mapping and decision frameworks used for managing new product development. An important aspect of the recent developments in new product development management is the renewed attention paid to bring the voice of the customer into the various stages of the process. They do not as yet formally provide room for incorporating the perhaps low level murmur of those who may not be customers but yet may feel that they will be profoundly affected by the new products.

Such murmurs may develop into a ground swell (e.g. the social movement organizations presented by Reisner (2001)) that may indeed lead to either the success or the failure of the new product under question. The strategy literature has indeed addressed the issue of stakeholder analysis that seeks to achieve the same goal, but it is surprising that it has not yet found itself in new product development processes. In the literature on product design and development (e.g. Ulrich and Eppinger, 1995) there is no formal framework linking technology, or scientific knowledge to possible products or product markets. In the strategic management literature there has been a growing body of literature that calls for properly valuing and leveraging the resources (both tangible and intangible) of a firm, as resources are said to be ineluctably linked to both enduring competitive advantage and rent (e.g. Amit and Schoemaker, 1993; Barney, 1991; Furrer *et al.*, 2001; Grant, 1991; Hall, 1992, 1993; Mahoney and

Pandian, 1992). Along with the growth in the focus on resources of a firm has also come the development of using real options value (the value of making a small investment in order to have an opportunity to be involved at a later stage) calculations to properly value the resources of a firm (Amran and Kulatilaka, 1999; Trigeorgis, 1996). Technologies and customers are considered important resources for firms. To determine the option value of a technology it is necessary to understand both the possible options for its application and the probability and value of success of each possible application. The value of a technology is its ability to be used in products that provide customer value and generate value for a firm. A framework that would enable a systematic understanding of the potential applications of a technology as well as the technology needed to fulfill customer needs would aid in determining and managing the value of the technology resources of a firm. The objective of this paper is to sketch out one possible framework that may serve as a platform for further research. The biotechnology industry is a rapidly growing industry. New research developments like the impending full mapping of the human genome are expected to lead to an enormous amount of new product activity that will benefit mankind and create value for firms. A framework for viewing and analyzing the links between science, technology and product markets is likely of considerable importance both to practitioners and scholars.

Two major insights from the literature underpin our framework. First is that the problem of linking a technology to product markets may be viewed hierarchically (Day, 1990). Starting from the top, a new product may be viewed as being composed of a bundle of different technologies. Each technology in a bundle fulfills a different function. A technology is selected for membership in a bundle from a set of technologies, called a technology building-block. All the members of a technology building-block can deliver the same functionality but differ otherwise. Second, the probability of a technology being used in a product depends on the probabilities of its being considered first as part of a relevant building-block, and then as part of the relevant bundle (Capon and Glazer, 1987). We postulate that boundaries hold back the consideration of a member of a set from being considered as a member of another set. Various boundaries, cognitive and otherwise, keep a technology from moving through the various intervening steps to being part of a product and thus define the probabilities of belonging to a set. The possible outcome depends on a bundle being introduced, the marketing context in which it is introduced and the strategy used for its introduction. We can foresee based on the recent experiences with the dotcom revolution that for-profit institutions will arise, each specializing in identifying and clearing out the boundaries that prevent the transition from one stage to the other and ultimately leading to new products. It is quite possible that many of the "experiments" (technology product links) not carried out may have had the biggest impact, had they occurred. By more systematically and comprehensively viewing the product creation process, perhaps, more experiments will be carried out. Bender and Westgren (2001) examine the social processes that drive the construction of the market(s) for genetically modified and non-modified crops. Our framework is intended to help to view and interpret the various levels at which social construction can, does and may take place by highlighting the various stages of the product creation process. It is entirely possible that the social processes that emerge at a higher (or closer to the market) level of our hierarchy of stages may be substantially dependent on the discourse and dialogue, and construction shaping done at earlier levels. It requires careful theoretical and empirical work to understand whether indeed later construction processes can be predicted by the semantics, syntax, and the context of discourse at the preceding level. The impact of construction at one level on another may not be unidirectional, but an interplay over time which shapes the emergence of new product markets by helping shape the cognitive boundaries of the feasibility and viability of incorporating an element from a lower level of the hierarchy in an entity at the next level.

The paper is organized in the following manner. First, we present a hierarchical process of product emergence and development. Second, we describe the development of a new product as the process of crossing boundaries, and discuss the example of the role of boundaries in the case of the development of the Flavr Savr™ tomato and other GMOs. Third, we present two processes to develop new products: a top-down process from product-variants to knowledge, and a bottom-up process from knowledge to product-variant. Finally, we conclude with the description of some implications of the framework. We use examples of GMOs to provide a unifying context throughout the paper. We wish to emphasize that our use of the Flavr Savr™ tomato example is just an illustration and does not describe the application, calibration, or validation of our framework.

A hierarchy of spaces in the process of product emergence

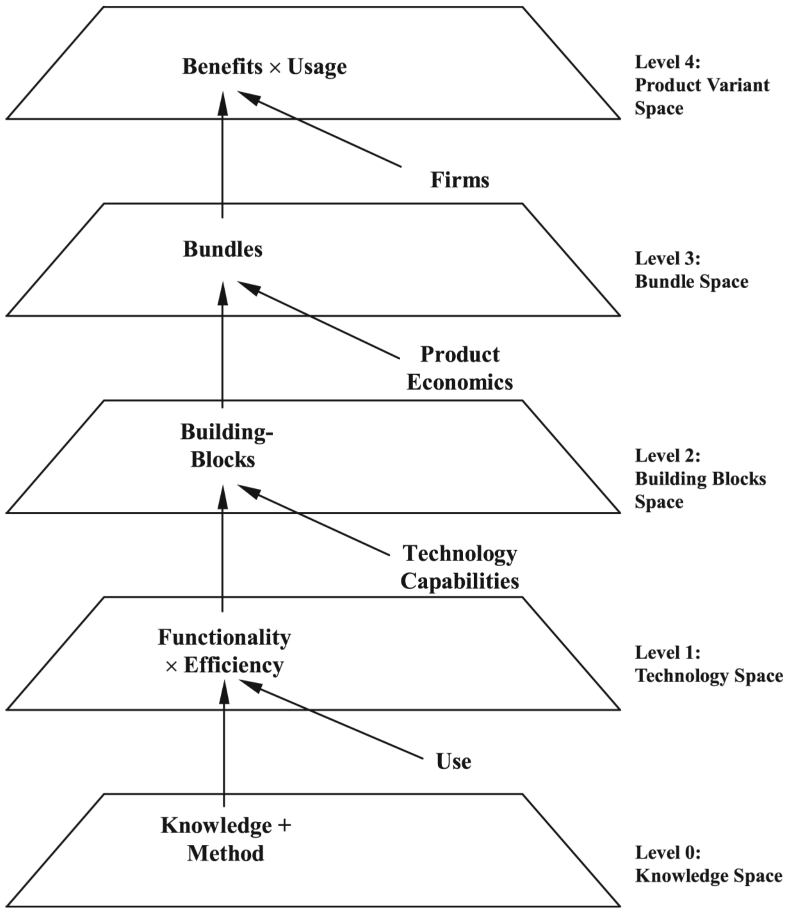
Products are made up of many technologies, and products succeed because they fulfill customer needs, are economically feasible and are socially acceptable. Old products are made obsolete by new products, but not all new products succeed, nor are all customer needs well satisfied. Many technologies are developed but are not incorporated into commercially available products, or at least may not be used to their fullest potentials. Therefore, we feel there is value to a representation of new product processes that will allow a broader view of the possibilities for new technologies as well as of market-opportunities and thus allow a better calibration of models calculating the real option value of a technology. Further, other participants, or would-be participants, could look at the knowledge development and anticipate the likely products that may or could emerge. Thus society could take more charge of the new product development process and not just the new technology development process, as is common practice. For example, again quoting from the US Senate report, "the advances in biotechnology have been made possible by the twin strengths of federally-sponsored medical research carried out by the National Institutes of Health (NIH) and other agencies, and the entrepreneurial leadership of about 1,300 US biotech companies."

While the idea of visualizing the existing linkages between technologies and products is not exactly a new idea (e.g. morphological analysis was first used by Zwicky (1969) and has also been written about by Tauber (1975), and Myers (1976)), that of decomposing the linkages into stages is new and, we feel, will enable a more detailed understanding of the commercial possibilities for technology use. So, our framework attempts to provide both an integrative (i.e. a bird's eye view of the technologies to new product link), as well as a systematic or step-by-step view.

Existing models focus on the process stages of new product development from a firm's perspective. For example, Cooper (1994) describes the stages of ideation, preliminary investigation, detailed investigation (or building a business case), development, testing and validation, full production and marketing launch, and post-implementation review. Each stage is followed by a go/no go decision. Ulrich and Eppinger (1995) divide the product development process into five phases. They are concept development, system-level design, detail design, testing and refinement, and production ramp-up. The concept development phase is further divided into eight steps. These are: identifying customer needs, establishing target specifications for a product based on the prior step, analysis of competitor products, concept generation, concept selection, refinement of specifications, economic analysis, and project planning. The above process of Ulrich and Eppinger may be called a top-down process. They also suggest that a bottom-up process may be used when a firm starts with a technology and builds it into a product. Our framework is complementary to that of Ulrich and Eppinger (1995) in that we provide a view that allows alternative technologies to be more comprehensively identified in attempts to fulfill customer needs in top-down processes and for alternative customer needs and segments to be more comprehensively identified in attempts to find the appropriate opportunities for a technology. It will thus allow for a better calibration of the option value of available technologies or technologies that may be pursued for further development.

For the purposes of visualization and analytical decomposition, we are of the view that competition for consumer demand occurs in the space of product variants (i.e. at Level 4 in Figure 1). Each element in the product variant space is an available product variant in the market. Each product is made using a bundle of technologies. The bundle used for a product-variant is chosen by a firm from elements in the technology bundle

Figure 1 Five-level hierarchy diagram



space. Thus, each element in the technology bundle space is a bundle of technologies. Each technology bundle is made up of various technology building-blocks, which have entered the bundle based mainly on design knowledge and economic considerations and are themselves elements of the technology building-block space. Some elements of the space of technologies become members of different technology bundles based on their functional capabilities being associated with specific bundles. An element of the technology space emerges as an element of the knowledge space is discovered to have a certain functionality associated with it.

The framework (see Figure 1) decomposes the overall process of movement from the discovery of a new knowledge element in knowledge space to its being incorporated into a new product, as the creation of new elements in various intervening analytical spaces. The space in which new products are represented is called product-variant space. These intervening spaces are labeled technology, technology building-block, and technology bundle respectively. We contend that, if a position in any of the above intervening spaces or the product-variant space is unoccupied, it is because of the existence of boundaries that prevent that position from being occupied by a new element[1].

At the base of the hierarchy is the space of knowledge. The elements of this space are discovered as the result of research efforts. Examples of results of these efforts in biotechnology are the discovery of Mendel's law, the DNA structure by Watson and Crick, or the function of each gene. An example of a conceptual mapping of knowledge space is provided by Pelc (1996, pp. 13, 17).

Each technology can be represented as addressing a particular functionality with a certain value of efficiency. These two dimensions are similar to those developed by Miller (1978) and Van Wyk (1996). So, the Technology space consists of all technologies that are represented by these two dimensions. An example of technology is antisense technology that relates antisense compounds to the blocking of specific proteins. The first dimension orders technologies based on their similarity on functionality. The second orders them based on their similarity on efficiency. The distinction made between knowledge and technology in our paper is the same as that made by Capon and Glazer (1987). They distinguish technology from the general notion of knowledge, and define technology as knowledge intended for a use. When a potential usage is ascribed to an element of the knowledge space, it along with its intended usage or function becomes an element of the technology space.

We define technologies that are considered for use in products as technology building-blocks. This term is similar to the usage by Meyer and Lehnard (1997). Technology building-blocks can be grouped into categories consisting of substitutes. For example, gene therapy and antisense technology are two elements of the same building-block. They may both be used to block the action of genes. Each technology building-block category can be viewed as consisting of a set of technologies that are similar in terms of their functionality and efficiency.

A collection of technology building-block elements that can be used jointly is called a technology bundle. A technology bundle will usually contain technologies from several technology building-block categories. Sometimes, more than one building-block from the same category may be present in the same technology bundle. Also, a technology may appear in multiple bundles. Different bundles may use the same building-block. For example, Remicade, used for the treatment of Crohn's disease, and Synargis, used to prevent serious lower respiratory tract disease caused by syncytial virus, both use the building-block monoclonal antibody technology.

The functionality and form of the resulting goods produced by using a technology bundle will depend on the production process and the mix of ingredients used. These goods, when combined with the marketing elements of branding, pricing, image, the choice of communications and distribution channels, and other services, are offered to customers.

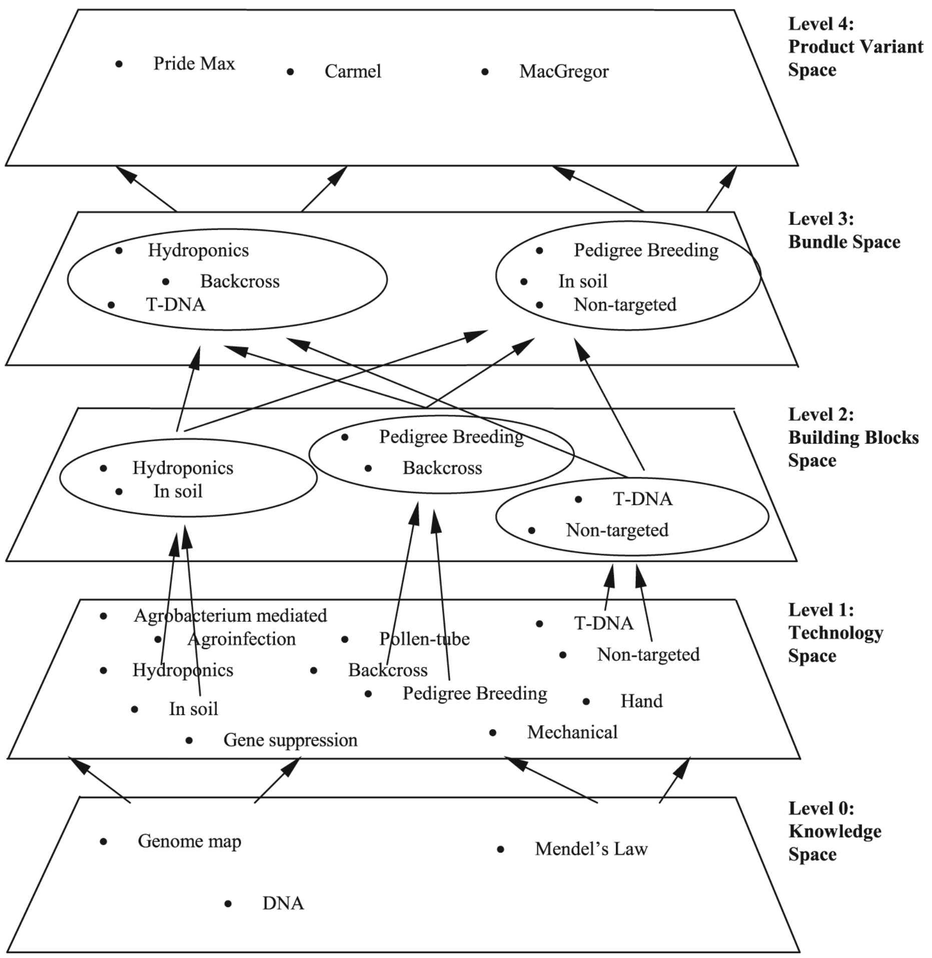
Customers are viewed as distinguishing between the alternatives offered to them in terms of benefits expected and the occasion(s) for which they can be used. Each alternative is referred to as a product-variant. This follows from the work of Haley (1968), Srivastava *et al.* (1978), Dickson (1982), Sheth *et al.* (1991), Urban and Hauser (1993), Sudharshan (1995), and Green and Srinivasan (1978).

Next, we provide (see Figure 2) illustrative tomato examples for each level of the framework.

At the Product-Variant level, tomatoes provide various benefits sought for by customers. The variants differ on the benefits they are perceived to offer and the usage (salad, cooking, etc.) for which they are perceived to be suited. Several tomato variants are commercially available. MacGregor's, Carmel, Hot House, Pride Max, and Grape brands in Roma, vine ripened, and plum varieties, and packaged in different weight units stand as examples of the various tomato variants that are offered to customers. The production of each of these tomato variants requires a different technology bundle. For example, the technology bundle required for the MacGregor's tomato variant is made up of a specific gene transfer technology (Agrobacterium-mediated transfer), a specific gene expression technology (called "antisense" gene technology), a traditional breeding technology, and other building-block technologies. The bundles for different tomato variants may be similar in that they require the inclusion of a technology building-block from the same technology building-block categories. They may differ in that each bundle may have a different building-block technology from the same technology category. For example, the MacGregor's tomato variant, like conventional variants, like the Hot House variant, needs a traditional breeding technology (Kramer and Redenbaugh, 1994). Other building-block categories are growing technology (e.g. hydroponics, in soil), harvesting technology (e.g. hand, mechanical), ripening (e.g. on the vine, artificial or ethylene-based ripening), etc. Some of the various technology building-blocks that make up the gene transfer technology category are Agroinfection technology, Agrobacterium-mediated technology, pollen tube pathway-based technology, etc. While various other gene transfer technologies may exist, only those technologies that practitioners consider for use become technology building-blocks.

It is important to understand that the members of each level of the framework may change over time. New knowledge and new technologies certainly do emerge. New

Figure 2 Five level hierarchy diagram



technology building-block categories are created over time, some possibly because of the re-categorization or because of the splitting-up of existing categories, and others because of the choice for use of new technologies that create their own categories. It is also entirely possible that a member of a technology building-block category will stop being a technology building-block. This may happen if it is surpassed by another technology because of functionality, or efficiency reasons, or other factors such as regulations and social resistance. An example of a technology that was a building-block technology but ceased to be one is the so-called "Terminator technology". This technology was developed by Delta and Pine Land (later acquired by Monsanto) to enable crops to kill their own seeds in the second generation (Crouch, 1998). Because of the social, economic, and environmental implications of this technology, several farmer and consumer associations launched a campaign against this technology. The opposition's campaign was so virulent that the company announced that it would not pursue the commercial development of this technology.

When a knowledge element is included as a technology, or a technology becomes a member of a building-block, or a building block technology becomes part of a bundle, or a bundle is commercialized by a firm, a new entity comes to exist in a particular position in the corresponding space. It is our view that the entity did not exist before because it was held back by one or more boundaries that held it from coming into existence. Therefore, we view the emergence of a new entity as the result of the crossing of one or more boundaries.

Boundary crossing

The existence of a product is delimited by technology boundaries, usage boundaries, needs boundaries, political boundaries, regulatory boundaries, etc. Boundaries of any kind within a space or across spaces may prevent the emergence of a new element. Some of the most important types of boundaries for new products are: scientific, technological, political, regulatory, economic, cultural, social, and cognitive boundaries. Our focus in this paper is on new product and market development through the process by which technology advancements lead to product-variants that when matched with customer needs lead to new markets.

One such example is the Flavr Savr™ tomato story[2]. In winter, most of the northern regions of the USA and Europe must rely on tomatoes shipped from the south. To withstand the rigors of shipping, tomatoes must be picked at a stage the growers call "mature-green." Mature-green tomatoes have already absorbed all the vitamins and nutrients from the plant that they can, but have not started to produce the natural ethylene gas that triggers ripening. To give tomatoes their natural red color, an operation called "degreening" or "ripening initiation" is necessary. This operation involves putting the green tomatoes in ripening rooms where ethylene gas is released. The green tomatoes spend three to four days in the ripening room before they are shipped. However, most consumers find that shipped-in winter tomatoes lack the taste and texture of vine-ripened tomatoes. There was a customer need that needed to be fulfilled. To solve this problem, Calgene, Inc., a biotechnology company with headquarters in Davis, California, has developed a tomato with a gene that slows the natural softening process that accompanies ripening. This genetically engineered tomato, called "Flavr Savr™," spends more days on the vine than other tomatoes, resulting in more flavor, yet remains firm enough to be shipped.

To develop this tomato, Calgene had first to understand how the ripening process works. It was the first boundary, in the Knowledge space, to be crossed. Pectin, used to make jelly thicken or gel, occurs naturally in many fruits, giving them their firmness. The pectin in ripening tomatoes is degraded by an enzyme called polygalacturonase (PG). As the pectin is destroyed, the cell walls of tomatoes break down and they soften, making them difficult, if not impossible, to ship successfully. Reducing the amount of PG in tomatoes slows cell wall breakdown and produces a firmer fruit for a longer time. Calgene's scientists isolated the PG gene in tomato plants and converted it into a reverse image of itself called an antisense orientation. The scientists called this "reverse" tomato gene the Flavr Savr™ gene and reintroduced it into tomato plants. Once in a tomato plant, with the Flavr Savr™ gene adhering to it, the PG gene cannot give the necessary signals to produce the PG enzyme that destroys pectin. With the specific work completed and a specific usage assigned to it, the isolation of the PG gene and its use for suppressing pectin-destroying signals in tomatoes became a member of the technology space.

The scientific boundaries in knowledge space were not the only boundaries that Calgene had to cross to bring the Flavr Savr™ to the market; other inter-level boundaries also had to be crossed before a new product-variant with the PG-pectin technology was available in the market, or emerge in the product-variant space. In 1992, Calgene, Inc. established a wholly owned subsidiary named Calgene Fresh, Inc. to produce, market, and sell high-quality branded fresh produce to the retail grocery and food service markets. Domestic consumption of fresh tomatoes was estimated at about 5 billion lbs a year with an estimated retail value of approximately $3-3.5 billion. Calgene Fresh, Inc. estimated that 85 percent of US households purchase fresh tomatoes each year, with more than 50 million consumers purchasing 3 lbs of fresh tomatoes in a typical month. This level of consumption was occurring despite consumer dissatisfaction with the quality of fresh tomatoes. It was felt that a need existed for a "fresher" tomato to be introduced based on Calgene's technology. Calgene had created the technology, but it was up to farmers to decide whether to include the new seed as part of their technology bundle in growing tomatoes for their markets. It is just as important for farmers to be conscious of the impact of the new technology on their market as it is for Calgene. It might be more difficult for farmers to diversify their risk relative to Calgene's ability to do so by working on several technologies. Other boundaries crossed are discussed below:

- *Resistance to intellectual property protection*: in February 1989, Calgene, Inc. was issued a US patent on the use of the tomato polygalacturonase (PG) gene sequence, including the antisense orientation of the gene. In April 1992, the company crossed a legal boundary between the building-block and bundle spaces when it was issued a broad patent covering the use of the antisense technology in all plants to partially or completely inhibit specific gene expression. However, other legal boundaries emerged as at least two companies challenged Calgene's patent for the Flavr Savr™.

- *FDA and USDA approval*: both the FDA and the USDA require a company to conduct rigorous pre-market testing of genetically engineered food products before they become commercially available. Flavr Savr™ underwent more than four years of comprehensive pre-market tests that examined its nutritional value, potential toxins, processing and horticultural traits, fungal resistance, softening rate, and other characteristics. At this stage the PG technology could be considered as part of bundles based on which product-variants could be introduced. In addition, Calgene Fresh, Inc. voluntarily submitted its safety data for rigorous review by an external panel of nationally recognized food safety experts. Their studies demonstrated the Flavr Savr™ tomato to be as safe and nutritious as other fresh tomatoes.

In October 1991, Calgene requested the FDA to issue an Advisory Opinion on the status of the Flavr Savr™ tomato as a food. To assure a thorough review of the safety of the new product, in May 1992, the company filed a Petition for Determination with the USDA requesting that the agency determine that the Flavr Savr™ tomato is a non-regulated article under federal law. In October 1992, the USDA determined that the Flavr Savr™ tomato did not present a plant pest risk and therefore need not be regulated.

In April 1994, outside experts of the FDA's Food Advisory Committee discussed the agency's evaluation of the Flavr Savr™ tomato in a public meeting. Members of the committee agreed with the FDA's preliminary assessment that all relevant safety questions about the new tomato had been resolved. On May 18, 1994, the FDA announced its findings that the Flavr Savr™ tomato is as safe as tomatoes bred by conventional means, in effect giving Calgene Fresh approval to market its new product. Calgene Fresh immediately began offering limited quantities of the new tomatoes grown from Flavr Savr™ seeds under the MacGregor's brand in selected Midwestern and California markets. This signaled the emergence of the PG technology into the product-variant space:

- *Customer acceptance*: Many boundaries had been crossed and a new product variant had emerged. However, the story does not end there. The Flavr Savr™ tomato was a good idea, but Calgene Fresh did not have access to the top commercial tomato variants (or cultivars). Therefore, they sold the Flavr Savr™ in limited quantities as a part of a non-premium tomato cultivar at a premium price. Meanwhile, between 1995 and 1997, Calgene was being bought up incrementally by Monsanto. In 1997, Flavr Savr™ production was stopped and Monsanto scientists began moving the genetic ripening trait into premium tomato variants. The company said that, because tomatoes are hybrids, this is a slow process and at the earliest a premium variety Flavr Savr™ tomato could be on the market again in two to three years. So, the bundles were not acceptable to the market, and new bundles would have to be conceived of and then introduced into the product-market space.

Not only should scientific and technology boundaries be crossed for a product to succeed, but also social and psychological boundaries should be crossed for the product to be accepted by the market. Nelson (2001) describes how consumers' risks and opportunities perceptions create such social and psychological boundaries. He shows that perception of dangers and opportunities of GMOs should be carefully managed for GMOs to be accepted by consumers. The importance of social and psychological boundaries can be illustrated by another example. In the case of the Terminator (RAFI, 1999), farmers perceived the dangers of adopting the "Terminator" technology as high, and the incremental opportunities resulting from its adoption as low. The boundaries that emerged once Terminator was introduced forced it to be retracted from the market. While the product was physically in the market, social and psychological boundaries kept it from being within the cognitive definitions of the market, and so led to its withdrawal.

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In March 1998, Delta and Pine Land Company (a seed company later to be purchased by Monsanto), in collaboration with the USDA, was awarded a patent over the control of plant gene expression. Although the patent was broad and covered many applications, one of these applications favored by the company was a scheme to engineer crops to kill their own seeds in the second generation. With a specific usage assigned to it, the knowledge became a technology. For the Delta and Pine Land Company, this technology had two important features:

(1) it prevented the dissemination of GMOs into the environment; and
(2) it made it impossible for farmers to save and replant seeds, thus obliging them to buy new seeds every year.

The usage was needed to fulfill the needs of Delta and Pine Land Company's seed-manufacturing customers.

This lock-up of the farmers pushed the Rural Advancement Foundation International (RAFI) to fight this technology that they nicknamed "Terminator." RAFI's campaign against this technology was so virulent that in October 1999 Monsanto announced that it would not pursue the commercial development of this technology (Goldsmith (2001) discusses the market power of GMO seed producers and describes other techniques used by producers to lock up farmers).

Such social and psychological boundaries have also affected the development of other biotech products. For example, biotechnology makes it possible for plants to protect themselves against certain insects. The protection comes from a naturally occurring micro-organism, called *Bacillus Thuringiensis* (or BT). BT has been used for more than 30 years by home gardeners, organic growers and other farmers. BT's DNA has been genetically engineered directly into corn, potatoes, cotton, and will soon be engineered into soybeans and other crops, to make them resistant to pests.

While bundles may be created incorporating these technologies, their emergence as product-variants will depend on corporate strengths in overcoming the social and psychological boundaries. Organic farmers are furious about BT crops, because they fear that the future is being endangered as pests will become resistant to BT and that more toxic pesticides than are being presently used will be needed in the future. Dozens of other farmers have joined with organic growers' organizations, Greenpeace, and other organizations in a lawsuit that seeks to revoke the registration of BT crops with the Environmental Protection Agency (Consumer Reports, 1999). There is also concern that BT farm products might affect other species in unknowing ways leading to a cascading set of environmental problems. Reisner (2001) shows that a wide variety of social movements may potentially be opposed to genetically engineered food. The first group, she presents, are social movement organizations directly concerned with "natural foods" or "natural agriculture" in all of its forms. But she shows that there are a wide variety of other types of movements that have adopted genetic engineering as an issue. The alternative agriculture movement, the environmental movement, the consumer movement and health movement, peace organizations, labor, human rights, international and nationalist, and animal rights organizations are already joining coalitions to oppose genetic engineering. That is, the usage of genetic engineering in agricultural and food productions has an unusually wide array of organizations opposing it. All these movements create boundaries to the development of genetically engineered food.

The fears of the organic growers have been supported by the findings of a study published in *Nature* by Losey *et al.* (1999). In this lab study, Losey and his colleagues reported that pollen from BT corn could spell trouble for the Monarch butterflies. In their experiment, they scattered pollen from BT corn on to milk-weed (the butterfly's only food during its larval or caterpillar stage) and noticed that the caterpillars that ate these leaves either died or were stunted (*Time*, 1999; Consumer Reports, 1999).

In the examples above, the technical and regulatory boundaries were successfully crossed, but the social and psychological ones could not be crossed. The importance of social and psychological boundaries is further illustrated by the announcements made on March 18, 1999 by seven large European food retail chains – among them Migros, Carrefour, Sainsbury's, and Marks & Spencer – in spite of initial strong, off-the-shelf

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performance, that they would not sell any product containing GMOs.

Other psychological boundaries that should be crossed by GMO producers are communication boundaries. More and more, governments worried about consumer reaction to GMOs have begun to impose labeling such products as containing GMOs. For example, in Switzerland, a new regulation was passed in January 2000 to oblige producers and distributors to properly label all products in which GMOs constituted more than 1 percent of the total contents. Such regulations will require GMO producers to communicate and convince consumers that their products are safe. That is, cognitive and social boundaries must be crossed. It was forecast that in 2000 the effect of the resistance of European and Asian consumers might force producers to reduce the surface used in 1999 to grow GMO crops by 25 percent. Juanillo (2001) argues for improved communication between the scientific community and the public to assess more accurately the risks of agricultural biotechnology and to reduce social and psychological boundaries to the acceptance of GM food and help governments to take more informed decisions. In Table I, we provide an example list of some of the requests for approval made to the USA for biotechnology products and the speed with which they were or are being approved.

In the above, we have provided examples and described new product development as a process of crossing various boundaries within and across levels. There are two canonical ways, top-down or bottom-up, by which new product emergence may be modeled and managed by systematically addressing the boundaries that either block or retard the emergence of new elements. We will next provide a stage-by-stage description of the two processes.

New product emergence: top-down and bottom-up processes

The top-down process starts, in its extreme case, with the identification of an open position in the Product Variant space. It leads to successive searches in the Bundle, Building Block, Technology and Knowledge spaces to develop the product-variant to be introduced. The bottom-up process starts with the emergence of a new element in the Knowledge space or in the Technology space. The new element is then linked upwards to the Product-Variant space through all the intermediary spaces. A knowledge element may be embodied in several elements of the Product-Variant space.

If a firm identifies a good market potential for seedless tomatoes, they will search for an existing technology bundle that could be used to serve this market. If such a bundle is not found (remember that it may exist but may not be found by the particular firm involved, due to the existence of knowledge or cognitive boundaries that prevent it from discovering such a bundle), growers will search for building-blocks that would allow this bundle to be formed. If the appropriate building-blocks do not exist, a new technology(ies) must be developed. The development of the new technologies required would be based on the combination of existing biology knowledge, agricultural knowledge, and other new knowledge developed from research projects.

A bottom-up process would start with the discovery of an element (or elements) in knowledge space. Prior to the experiments conducted by Mendel in the late 1850s and early 1860s, there was a scientific boundary (i.e. lack of knowledge) that would not allow systematic plant hybridization. With advances in knowledge of the structure of DNA, in other words, with the crossing of knowledge boundaries, scientists could investigate the functions of different genes. With the discovery of the uses of such knowledge for gene transfer, gene isolation and the ability to carry out both routinely, new technologies were born. These genetic engineering technologies could now be bundled with technologies from other building-block categories such as growing, harvesting, ripening, etc. Firms could decide to create product-variants from such bundles. Other types of boundaries also play important roles in the example of GMOs. A good example is the FDA approval regulatory boundary that needs to be crossed for bringing drugs and foods to the market in the USA. Other countries have similar organizations for approving such products. In the case of GMOs cultural and social boundaries made consumers reluctant to accept products that were genetically altered. These boundaries

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Table I Requests for approval made to the USA for biotechnology products

Company	Application	Plant	Type of alteration	Effect	Result	Date of result
Aventis	99	Rapeseed	Herbicide tolerant	Bromoxynil tolerant	Withdrawn	00
Bejo	97	Chicory	Agronomic properties	Male sterile	Withdrawn	00
DNA Plant Tech	94	Tomato	Product quality	Fruit ripening altered	Withdrawn	99
Monsanto	97	Potato	Insect resistant	Colorado potato beetle resistant	Approved	00
			Viral resistant	PLRV resistant		
Mycogen	99	Corn	Insect resistant	European Corn Borer resistant	Withdrawn	99
Monsanto	97	Potato	Insect resistant	Colorado potato beetle resistant	Withdrawn	99
			Viral resistant	PLRV resistant		
Agritope	98	Melon	Agronomic properties	Fruit ripening delayed	Withdrawn	99
AgrEvo	95	Corn	Agronomic properties	Male sterile	Approved	99
			Herbicide tolerant	Phosphinothricin tolerant		
U. of Saskatchewan	98	Flax	Agronomic properties	Tolerant to soil residues of sulfonylurea	Approved	99
AgrEvo	98	Rice	Herbicide tolerant	Phosphinothricin tolerant	Approved	99
AgrEvo	98	Rapeseed	Agronomic properties	Male sterile	Approved	99
			Herbicide tolerant	Phosphinothricin tolerant		
AgrEvo	98	Soybean	Herbicide tolerant	Phosphinothricin tolerant	Approved	98
Monsanto	98	Rapeseed	Herbicide tolerant	Glyphosate tolerant	Approved	99
Novartis Seeds	98	Beet	Herbicide tolerant	Glyphosate tolerant	Approved	98
AgrEvo	96	Soybean	Herbicide tolerant	Phosphinothricin tolerant	Approved	98
Pioneer	97	Corn	Agronomic properties	Male sterile	Approved	98
			Herbicide tolerant	Phosphinothricin tolerant		
Monsanto	97	Potato	Insect resistant	Colorado potato beetle resistant	Approved	99
			Viral resistant	PVY resistant		
Monsanto	97	Potato	Insect resistant	Colorado potato beetle resistant	Withdrawn	97
			Viral resistant	PVY resistant		
AgrEvo	97	Beet	Herbicide tolerant	Phosphinothricin tolerant	Approved	98
Monsanto	97	Tomato	Insect resistant	Lepidopteran resistant	Approved	98
AgrEvo	97	Corn	Herbicide tolerant	Phosphinothricin tolerant	Approved	98
			Insect resistant	Lepidopteran resistant		
AgrEvo	97	Rapeseed	Herbicide tolerant	Phosphinothricin tolerant	Approved	98
Monsanto	97	Potato	Insect resistant	Colorado potato beetle resistant	Approved	98
			Viral resistant	PLRV resistant		
Bejo	97	Cichorium intybus	Agronomic properties	Male sterile	Approved	97
Monsanto	97	Corn	Herbicide tolerant	Glyphosate tolerant	Approved	97
AgrEvo	97	Rapeseed	Herbicide tolerant	Phosphinothricin tolerant	Withdrawn	97
Monsanto	97	Cotton	Insect resistant	Lepidopteran resistant	Withdrawn	97
Calgene	97	Cotton	Herbicide tolerant	Bromoxynil tolerant	Approved	97
			Insect resistant	Lepidopteran resistant		
Du Pont	97	Soybean	Product quality	Oil profile altered	Approved	97
AgrEvo	96	Rapeseed	Herbicide tolerant	Phosphinothricin tolerant	Withdrawn	97
Du Pont	96	Soybean	Product quality	Oil profile altered	Withdrawn	96
Monsanto	96	Corn	Herbicide tolerant	Glyphosate tolerant	Withdrawn	97
Monsanto	96	Corn	Herbicide tolerant	Glyphosate tolerant	Approved	97
			Insect resistant	European Corn Borer resistant		
DeKalb	96	Corn	Insect resistant	European Corn Borer resistant	Approved	97
Calgene	92	Tomato	Product quality	Fruit ripening altered	Approved	96
Monsanto	96	Corn	Herbicide tolerant	Glyphosate tolerant	Withdrawn	96
			Insect resistant	European Corn Borer resistant		
DeKalb	96	Corn	Insect resistant	European Corn Borer resistant	Withdrawn	96
AgrEvo	96	Soybean	Herbicide tolerant	Phosphinothricin tolerant	Approved	96
Cornell U.	96	Papaya	Viral resistant	PRSV resistant	Approved	96
Monsanto	95	Corn	Insect resistant	European Corn Borer resistant	Approved	96
Cornell U.	95	Papaya	Viral resistant	PRSV resistant	Withdrawn	96
Asgrow	95	Squash	Viral resistant	CMV resistant	Approved	96
			Viral resistant	WMV2 resistant		
			Viral resistant	ZYMV resistant		
Monsanto	95	Potato	Insect resistant	Colorado potato beetle resistant	Approved	96
AgrEvo	95	Soybean	Herbicide tolerant	Phosphinothricin tolerant	Withdrawn	95
Agritope	95	Tomato	Product quality	Fruit ripening altered	Approved	96

also need to be crossed for the success of a new product.

The bottom-up and top-down processes, described above, are mainly concerned with how a gap at any level is filled using elements from levels below it. So, a new product variant may emerge based on either existing or new bundles. A new product-variant based on a previously known bundle can change the product market landscape to some degree. A new product is likely to emerge as a result of a novel bundling of technologies by combining technologies from categories not combined before, or by incorporating a technology from a newly emerged technology building-block category. The benefits and usage occasions served by new products are also likely to be distinctly different from those being served in the market and thus are likely to lead to new product categories and product markets.

Conclusion

Some of the implications of the framework may be viewed in the context of the top-down and bottom-up processes of emergence that we just discussed. To use a top-down process, a manager is expected to start with identifying a gap in the Product-Variant space. The first question to be asked is "Why does the gap exist?" In other the words, what boundaries are protecting that location from the emergence of an element there? Is the gap because of need boundaries? Is it because customers do not perceive the need for a product variant that would fill the identified gap? If so, a latent need has perhaps been identified. A latent need is very likely to be associated with customer perceptual boundaries in product-variant space. It is also very likely to be associated with boundaries at other levels that either exist or have existed till quite recently. If it is anticipated that the identified gap is associated with an adequate market potential, then analysis and resource allocation can be performed and devoted, respectively, to the appropriate spaces of the other levels of the product-market hierarchy. Strategic planning would then involve the understanding and documentation of the locations, strengths and types of boundaries and their dynamics. Then, attempts at crossing boundaries in Building-Block, Technology, or Knowledge spaces could be based on the expected dynamics to achieve the goals set for the Product-Variant space.

If a new knowledge element emerges then its value can be assessed by systematically following the path of its similar or related knowledge elements across the levels of the product-market hierarchy. A fuller set of alternatives and their associated probabilities generated by the systematic process will allow for a better valuation and decision. By explicitly understanding the links, and the benefits that will be delivered, a manager will have richer information. By comprehending the nature of the boundaries present:

- a manager can allocate resources to their crossing;
- understand how the market of interest is likely to change over time; and
- incorporate the understanding of both gaps in the spaces and likely scenarios in strategic planning.

Another implication of this paper is the use of the hierarchical framework to identify the connections between elements of different levels that point to clear changes in the market. A change in the technology space may represent changes in more than one domain of product-variants that use the same technology as a building-block. In some other circumstances, a change in the technology space element that is used in different product-variant domains could also break the link between these product variants if the new technology dominates the old one for one product variant domain and not for the other.

Finally, the representation of the boundaries that define the existent set of elements in each space level, and the understanding of the impact of crossing each boundary, may help a firm to identify its technology and new product priorities and thus the direction that its efforts should take.

We have presented an integrated framework for the study of the development of new products. Our discussion has used several examples from the biotechnology industry. The framework provides an exposition of the primary level-by-level decomposition of the problem of new product emergence from new knowledge to technology, to technology building-blocks, to technology bundles, to new product variants. We have detailed bottom-up and top-down processes for product-market emergence, and discussed managerial implications using these processes as guidelines.

The biotechnology industry is relatively young. The associated knowledge discoveries are occurring at a heightened pace. The connections between scientific knowledge and product variants are not well-known. The knowledge elements may yet not have become technology elements, let alone be introduced as product-variants. There is a need for being able to put a value on the various knowledge elements or even technologies to identify priorities for further resource allocation. By better identifying the possibilities associated with each, and by thinking through and developing the associated probabilities, better valuations, through real options analysis, may be possible. The consideration of a technology as a member of a building-block set may open a whole host of bundle and product-variant possibilities. In the biotechnology industry, the value of real options analysis is likely to be high and a need exists for a framework such as the one presented in this paper to make better possible calibration of such analysis and therefore lead to better resource allocation decisions.

Several research questions remain to be raised and answered. For example, methodologies for operationalizing the framework (a combination of mental mapping, environmental analysis, multidimensional scaling of similarities/dissimilarities, and stochastic process modeling) need to be carefully articulated and tested. Theoretical propositions need to be developed for the emergence of the types and positions of new products and new product-markets. The nature of social organizations that can or should emerge to better direct the development of new products needs to be studied. These organizations may provide the language through social construction with which the entities at each level of the hierarchy are cognitively accessed, addressed, and processed. The interaction between discourses at the various levels needs to be studied. For example, how does the type of approval provided by a regulatory body affect the limit or broaden the possibilities for a new technology? Cutting off the development process too early may lead to a tremendous opportunity cost; on the other hand, not cutting off some developments may lead to tragedy. Natural social processes may sometimes be too slow at recognizing and responding to danger before it is too late – the danger either of lost opportunity or of tragedy. We need to study how social knowledge management systems may be built so as to facilitate wise choices in the movement of science to new products.

Biological processes contain technologies that perform every function known to man. Biotechnological processes, therefore, have the possibility of affecting every type of product in the marketplace, from food, to transportation, to books, to computing, to energy sources, to entertainment. At the same time, societies may perceive themselves to have less control of the environmental impact of the results of the usage of biotechnology-based products compared with products based on other technologies. In the language of our framework, it would appear that a key part is missing from the bundle necessary for product success. This would be a control technology. To find a control technology, the appropriate building-block space should be searched for and, if no candidate exists there, then efforts should be directed at the appropriate-level technology or basic research to create the necessary building-block technology(ies). It is important to ensure that boundaries be anticipated and managed. Or that they be quickly identified and managed. We go out on a limb, because of our belief in technology, that it is more than likely that the solution to crossing a boundary lies in either adding or subtracting technologies from the technology bundle used to create products for the marketplace. As mentioned in our introduction, new product development is often a long and arduous task. The rewards are high both to individual corporations and to their shareholders, but also to society at large. The consequences may be serious of delaying the development of new products or of the failure of new products because they have important benefits but do not have the necessary technology to combat their ill effects (see Table II).

provides a few examples of the time from science to new products. We hope that a proactive management of the boundaries that prevent scientific knowledge from being embedded in products will shorten the time taken as well as lead to products that are successful and are beneficial to consumers. We hope that our framework contributes in some way to a better understanding of the link between science and new products and provides support to human creativity and

Table II Time from Invention to commercialization of some technologies

Silicone	Insulin	Magnetic recording
1899 – first published paper on organo-silicon	1920 – first ideas for extraction of insulin	1893 – magnetic recording was invented
1930 – first silicones could be produced in laboratory	1922 – first human patient received insulin	1898 – magnetic recording was patented
1946 – General Electric produced silicone commercially	1933 – production of the full-day insulin supply in one injection	1937 – first tape recorder was produced

entrepreneurship in improving the quality of life on this planet.

Notes

1 Elements in knowledge space may need to be viewed somewhat differently. From a phenomenological perspective, it may be argued that all things knowable already exist, but that boundaries prevent them from being known. The main focus of our paper is on the other spaces.
2 This story is based on the article written by Glenda D. Webber (1994): "Genetically engineered fruits and vegetables'' that is available on the Internet at the following address: http://biotech.iastate.edu/biotech_info_series/bio8.html and several other press articles.

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