From Crops to Cures

Intellectual-Property Considerations for the Emerging "Pharming" Industry

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Using genetically modified plants, animals, or microbes as living bioreactors, "pharming" is poised to disrupt biopharmaceutical manufacturing. Although bioproduction methods in living systems have their difficulties (e.g., variability from environmental conditions), pharming offers faster scale-up, lower costs through reduced cold-chain logistics, and lighter environmental footprints than are associated with conventional protein expression systems, such as engineered Chinese hamster ovary (CHO) cells. Such systems can be designed to consume less water and energy while minimizing waste, reducing contamination risks and carbon emissions (**1**).

Analysts forecast robust growth across pharming sectors. Estimates predict that the global biotechnology industry could exceed US$3.5 trillion by 2033 (**2**), with plant, animal, and microbial pharming each showing steady compound annual growth rate (CAGRs) of 7–10% (**3–5**). Sitting at the crossroads of agriculture, pharmaceuticals, and biotechnology, pharming also introduces a uniquely complex intellectual property (IP) landscape that demands thoughtful and robust protection strategies. Innovation entails not only developing new drugs, but also engineering novel organisms and cultivation/purification methods. Protecting such multifaceted inventions requires strategic IP management that might involve patents and other safeguards for trade secrets.

For example, a "pharmed" crop might itself be a patented variety, raising "essentially derived" variety questions under plant breeders' rights (**6**). Freedom to operate must be evaluated across patents on seeds, transgenes, and even farming processes, while overlapping agricultural and pharmaceutical regulations add further complexity.

Innovation for Plant-Based Pharmaceuticals

Genetically engineered plants could revolutionize drug production by serving as factories for therapeutic proteins, vaccines, and enzymes. Transgenic crops enable low-cost upstream production and significant potential for scale-up through open-field

Back to Contents

Plants such as *Nicotiana benthamiana* (pictured) for "pharming" are poised to disrupt biopharmaceutical manufacturing with their fast scale-up, low costs, and light environmental footprints.
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cultivation. Such benefits could reduce costs dramatically if appropriate downstream-processing methods are implemented. For example, seed-based expression systems can provide a favorable environment for storing biomass containing recombinant proteins for long durations at ambient temperatures, thus uncoupling upstream production from downstream processing and facilitating purification on demand (**7**).

A commercially successful example of plant-based recombinant protein production is Medicago's *Nicotiana benthamiana* platform, which enabled production of the Covifenz COVID-19 vaccine in 2022 (**8**). The rapid development and Health Canada approval of the vaccine platform underscores how quickly plant systems can be used as additional avenues for therapeutic production in response to pandemics (**8**). Likewise, plant-made influenza vaccine candidates have shown strong immunogenicity, validating transgenic crops' capacity to create viable human vaccines (**9**).

From an IP perspective, plant-based production enables innovators to patent not only final products, but also enabling technologies. Medicago, for instance, received patents for expression enhancers to boost transgene yields (**10**), protein-extraction technologies to improve purity (**11**), and glycoengineered *Nicotiana* lines to produce humanized proteins (**12**). However, patent applications become publicly available after 18 months. Therefore, a competitive edge can be gained by keeping certain aspects of production and purification systems secret.

A vaccine grown in tomatoes or a therapeutic antibody expressed in a chicken's egg is more than a breakthrough product — it represents the **CONVERGENCE** of agriculture, biotechnology, and pharmaceuticals.

Animal Pharming: Biofactories of the Future

Animal pharming uses transgenic livestock such as goats, cows, chickens, and rabbits to produce therapeutic proteins in their milk, eggs, or blood. Transgenic livestock can be highly efficient and cost-effective "bioreactors" because they can produce large quantities of complex therapeutic proteins that are biologically active and correctly folded (**13**).

One leading success is Pharming Intellectual Property BV's Ruconest recombinant complement protein 1 (C1) esterase inhibitor, a drug produced in rabbit milk and approved by the US Food and Drug Administration (FDA) to treat hereditary angioedema (**14**). Similarly, goats and cows have been engineered to express antibodies in their blood and secrete proteins such as antithrombin in their milk, offering the potential for high-volume biologic production.

Related patents cover DNA constructs, promoters, modified animal lines, and purification methods. The developer of Ruconest protects both the recombinant protein and the transgene used to enable its expression in rabbit milk (**15, 16**). In addition to patents,

trade secrets often safeguard breeding techniques and herd-management practices. Internationally, animal pharming raises additional hurdles, however. Some jurisdictions restrict patents on higher lifeforms, pushing companies to focus their claims on genetic sequences or methods. A layered IP strategy to balance patents and know-how is therefore essential.

Strategic IP Protection for Pharming Companies

Back to Contents

Whether a large biopharmaceutical company or an emerging agritechnology start-up, all pharming organizations must be deliberate in protecting their innovations. The goal is twofold: to secure rights that attract investment and partnerships and to maintain a lasting competitive edge. Such a balance requires a thoughtful mix of patents and trade secrets.

Securing Exclusive Rights and Licensing Opportunities: Patents remain the backbone of pharming IP strategy. They provide exclusivity, create valuable licensing opportunities, and reduce investor risk by signaling market control. Because pharming platforms are designed to be versatile, innovators must look beyond narrow product claims to pursue broader protection, covering host organisms, expression cassettes, purification systems, and other enabling technologies.

For example, Medicago's portfolio layered protection around its plant-based vaccine technology. That protection currently extends to Aramis Biotechnologies, which inherited the former company's IP in the wake of its 2023 closure. *Diamond v. Chakrabarty* (1980) confirmed the patentability of genetically engineered organisms in the United States; however, that is not the case in many other jurisdictions. Strong portfolios not only deter competitors, but they also underpin strategic partnerships and licensing deals that expand commercial reach.

Protecting Trade Secrets Behind Platforms: Not every innovation should be patented. Competitive advantages such as optimized growth conditions, purification recipes, cultivation techniques, processing steps, and stability enhancements may be better safeguarded as trade secrets. Unlike patents, trade secrets can last indefinitely if confidentiality is maintained.

For pharming, where yield optimization and process efficiency are critical, the most effective strategies combine patents for core inventions with trade secrets for refinements. Protecting such information requires restricted access, robust internal protocols, and confidentiality agreements with employees, collaborators, and suppliers. Those practices can ensure that know-how remains proprietary while still enabling collaboration.

Building Value Through Collaboration: Because pharming is a cross-discipline involving agriculture, pharmaceuticals, and biotechnology, partnerships are essential. Clear IP ownership and enforcement clauses are as critical as the patents themselves. iBio's FastPharming platform illustrates that principle: Collaborations have yielded new patents on therapeutic antibodies and glycosylation modifications while leveraging trade secrets to protect platform know-how (**17, 18**).

Cross-licensing and joint development can accelerate innovation, but agreements must ensure that resulting technology confers a competitive edge, either through exclusivity or favorable licensing terms. Given the overlap between agricultural patents on crops and pharmaceutical claims on biologics, rigorous freedom-to-operate analyses are especially important in the transgenics space.

Protecting Innovation Across Borders: A vaccine-producing crop might be engineered in one country, cultivated in another, and sold worldwide. Companies therefore should leverage the World Intellectual Property Organization (WIPO) to secure coverage in multiple jurisdictions, while tailoring filings to national laws that may restrict patents on living organisms. At the same time, trade secrets can provide a backstop, ensuring that even if protections differ across borders, proprietary know-how remains shielded from competitors.

Embracing the Future of Pharming Through Smart IP Strategy

Pharming stands at the innovative intersection of farming and pharmaceutical production, offering a bold vision for the future of drug manufacturing. Its applications — e.g., to create vaccines in greenhouse-grown plants and therapeutic enzymes in goat's milk — could reshape global healthcare by making essential medicines more accessible and sustainable than before. As the field rapidly evolves from intriguing experiments to commercial reality, companies at the forefront recognize that technology alone is not enough; it must be matched with astute IP strategy.

The most successful innovators layer their protections — patents for genetic constructs and production technologies, trade secrets on proprietary refinements, and global filings aligned with commercialization plans. Such an integrated approach not only preserves competitive advantage, but also creates the clarity and confidence that investors and partners demand.

In the decade ahead, pharming could shift how we think about biomanufacturing. A vaccine grown in tomatoes or a therapeutic

Back to Contents

antibody expressed in a chicken's egg is more than a breakthrough product — it represents the convergence of agriculture, biotechnology, and pharmaceuticals. Those who cultivate innovation and strategically protect it will be best positioned to harvest the rewards.

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Back to Contents

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