

Innovation in Agricultural Technology: Strategic Considerations

Jennifer Giordano-Coltart and Megan Lyman



Agriculture

10,000-year-old industry
Feeding 10B people by 2050
(affects each of us ~3x a day)

Climate change and its effect on growing

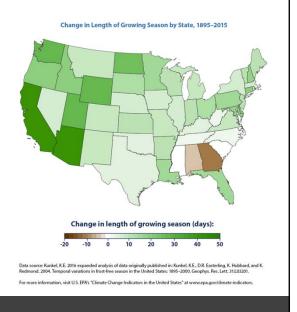
Agriculture's role in climate change





Changing Growing Season

- Shifting industry changing arable land
- Traditional land in the Midwest experiencing changes in temperature that affect ability to grow wheat, corn, soy – moving north in Canada
- Rising temperatures in Southeast disrupt crop growing – reliance on indoor farming
- Warmer climates promote infiltration of pathogens once limited to South America





3

AgTech v. Human Health

AgTech evolving following footsteps of Pharma

Similarities

- Consolidation
- Acquisition-based pipeline/External innovation
- Product development timeline/cost
- Less investment funds
- Diverse/larger syndicates
- Differences
- Higher investor education barrier
- Investment amounts (~10x less)
- ROI (5-10x less)



AgTech: Select Sectors







Plant fitness/ improvement



Novel Farming Systems



Animal Health



Innovative Food



Agribusiness



Digital Ag



_

Definitions

GMO: Genetically modified organism; introduction of new DNA into organism; results in an organism with a new characteristic (in plants, called a "trait")

Gene Editing: Altering the normal DNA of an organism using biotechnology to result in a new characteristic/trait

Breeding: Cultivating plants or breeding animals to develop a desired characteristic/trait

Biologics: active compositions typically made using biotechnology methods – proteins, natural or engineered microorganisms, fermented products (e.g., metabolites); contrast to chemically synthesized small molecules.

Nucleic Acids: RNAs and DNAs; genetic material that encodes proteins or has other functions (e.g., cDNA, mRNA, RNAi, dsRNA)

Vertical Farming: growing plants in a controlled-environment in vertically stacked layers; a sector of indoor farming

Aquaculture: rearing of aquatic animals or cultivation of aquatic plants for food





Crop Protection

Pesticides: Herbicides, Insecticides, Fungicides

Issue

- Loss of 50% in wheat and 80% in cotton without pesticide use¹
- Lack of innovation majority of treatments were developed near WWII

Approaches

Small molecules, nucleic acids, biologics, traits



Popp, J. et al., Pesticide productivity and food security. A review. Agronomy for Sustainable Development 33::243-255 (2013)



 $Photo \ Source: \ https://www.kenresearch.com/blog/2020/12/growing-insights-of-crop-protection-market-outlook-ken-research/ \\ 7$



Plant Fitness/Improvement

Drought/saline resistance, yield maximization, nitrogen/phosphorous efficiency

Issues

- Adaptations to environmental pressures/climate change
- Regulatory pathway faster (or not needed)

Approaches

 Microbial discovery/editing, small molecules, biologics, gene editing, breeding, epigenetics





Photo Source: https://www.happysprout.com/gardening/trace-mineral-soil-gardening/



Novel Farming Systems

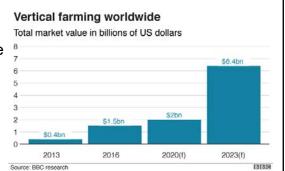
Vertical/Indoor Farming, Aquaculture

Issues

- Seeds adapted for outdoor cultivation
- Infrastructure lighting, harvesting, software
- Contamination ability de-contaminate
- Optimizing Conditions growth, yield, media, nutrients

Approaches

 New materials for growth, software, breeding, AI (machine learning), hydration systems, automation





 $Photo \ Source: \ https://www.inc.com/jenna-broughton/bowery-snags-20m-to-fund-the-future-of-farming.html$



Animal Health

Livestock, companion, equine

Issues

- Regulatory considerations
- Interplay with human health market
- Antibiotic resistance/use restrictions

Approaches

- Small molecules, biologics, gene editing
- · Vaccine development/deployment
- · Health sensors biometrics, mobility





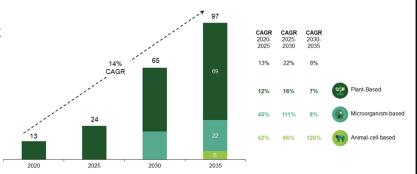
Photo source: https://www.planning.org/knowledgebase/urbanlivestock/



Innovative Food

Cultured meat, Novel ingredients, Plant/Insect-based protein

- Multisegmented market
- Consumer driven
- Perception v. Reality
 - Sustainability
 - Cost parity
 - Health



Consumption of alternative proteins by source (million metric tons, base-case scenario)



https://www.foodnavigator-usa.com/Article/2021/03/24/Alternative-proteins-will-account-for-11-of-global-protein-market-by-2035-predicts-report



Innovative Food

Cultured meat, Novel ingredients, Plant/Insect-based protein

Issues

- Complex regulatory approvals/labelling
- Consumer Preferences: heme-producing plants, texture, taste, physical properties

Approaches

 Specialized manufacturing, gene editing, breeding systems





 $Photo\ Source: https://www.azocleantech.com/article.aspx? Article ID=683$



Agribusiness

Seed selection, production, food safety, traceability, farm management, processing technology, leasing, insurance

Issues

- Servitization
- Adoption, data privacy
- · Carbon credit management

Approaches

Software/hardware, automation





Picture Source: https://medium.com/@andrewagdna/five-trends-that-are-transforming-your-farm-1-cloud-computing-b18402cad91a 13



Digital Agriculture

Drones, sensors, grow equipment, harvesting equipment

Issues

- Integration
- · Meaningful/useful display of data
- Automation
- Data privacy

Approaches

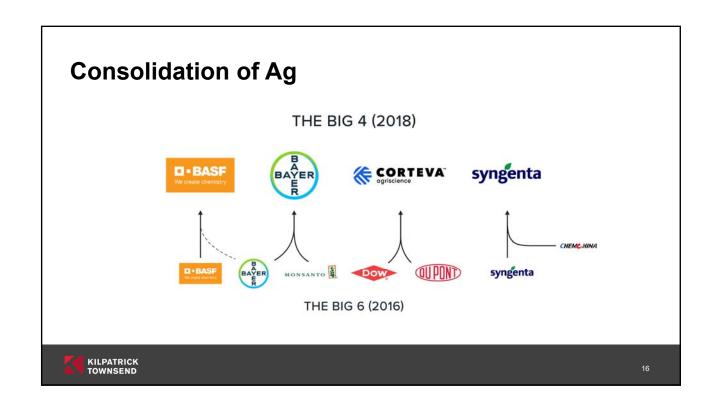
- Software/hardware, robots
- Geo-referenced maps based on public records (weather, soil, topography), satellite images
- Crowd sourcing farmers

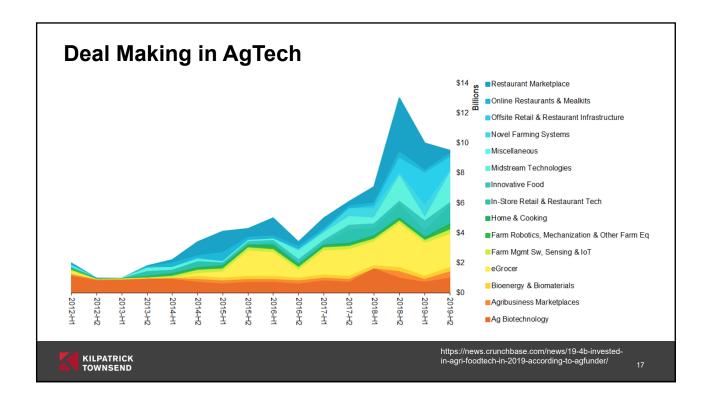




Picture Source: https://www.futurefarming.com/Machinery/Articles/2019/11/21-autonomous-tractor-projects-around-the-world-501448E/







Value of Intangible Assets - Intellectual Property

Intangible Assets have risen from 17% to 90% of value in the S&P 500 from 1975-2020

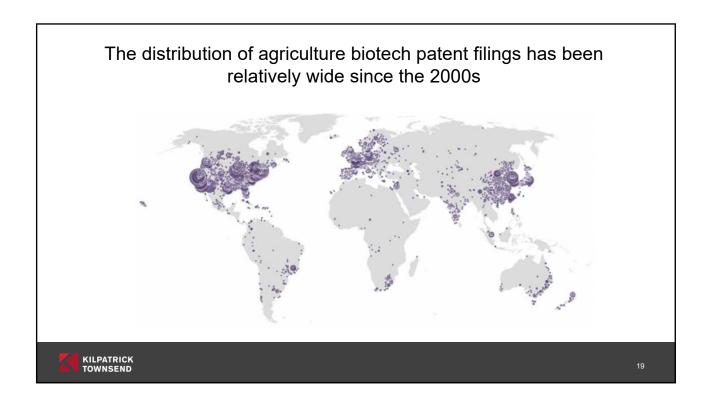
Tangible Assets

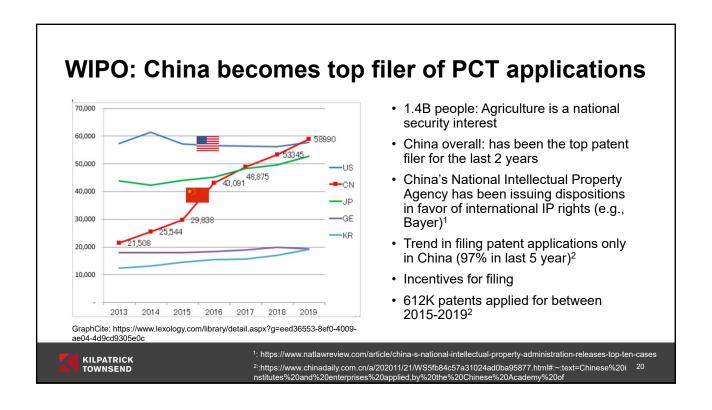
- · Buildings & equipment
- · Cash and bonds
- Inventory

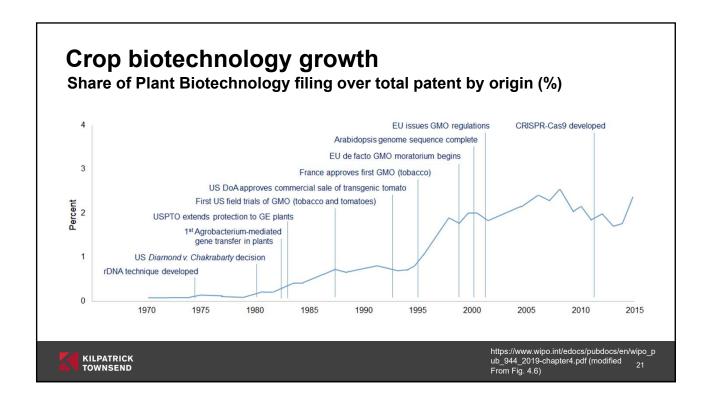
Intangible Assets

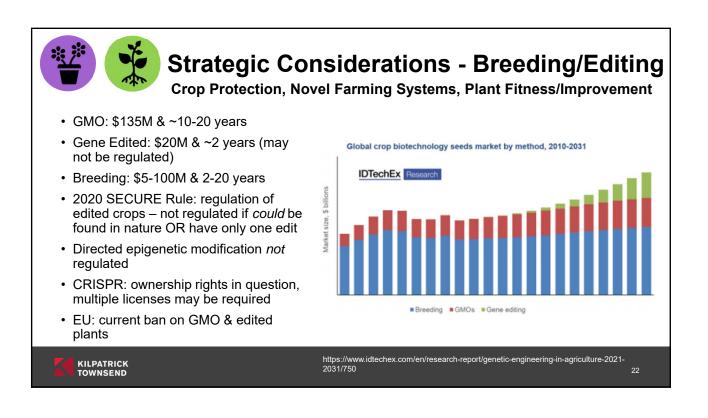
- Patents
- Trademarks
- Copyrights
- Trade Secrets
- Licenses
- Consumer data















Strategic Considerations - Breeding/Editing

Crop Protection, Novel Farming Systems, Plant Fitness/Improvement

In addition to utility patents gene edited/GMO plants, other plants protections are:

PVP: Plant Variety Protection – 25-year protection

- New, distinct, uniform, stable, sexually reproduced or tuber propagated plant varieties
- Exemptions: farmers may bulk seed for own use, if deemed necessary by USDA, for research purposes

Breeder's Rights – 20/25 year protection*

- Under TRIPS (members of WTO) new, distinct, uniform, stable variety of any plant species
- Owner has rights to production or reproduction, conditioning, exporting, importing, stocking
- *woody plants: 25 years

Plant Patents – 20-year protection

- Asexually reproduced (other than tuber or noncultivated), algae and macro-fungi (not bacteria) included
- Deposits required, not available in many jurisdictions



23



Strategic Considerations - Crop Protection

Pesticide: "Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. Any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant."

	Synthetic Chem	Biologics	Nucleic Acids
Cost/Time	\$130M & 10 years	\$20M & 5 years	\$20M & 5 years
IP	Thickets where no COM	101	101
Lifecycle management	✓	✓	✓
Regulatory EPA	✓	✓	✓
Int'l crop market selection	✓	✓	✓
Manufacturing	Int'l	Domestic	Domestic
EU ban considerations	✓	-	-
Patentability issues	-	✓	✓





Strategic Considerations - Animal Health

- Costs for a new active ingredient¹:
 - · Companion Animals: \$22.5M and 6 years
 - · Livestock: \$30.5M and 8 years
- Regulatory:
 - Different agencies for different products:
 - Pharmaceuticals: FDA Center for Veterinary Medicine (CVM)
 - · Biologics (e.g., vaccines): USDA
 - · Pesticides (e.g., flea, tick): EPA
 - · Gene modified animals: FDA and USDA
 - Generic Animal Drug and Patent Term Restoration Act: all approved animal drug products are listed in the Green Book; 5 years exclusivity of an approved human therapeutic for animal use
- Licensing from human health, IP freedom to operate, royalties, and clearance
- IP Lifecycle management follow-on filings for delivery, formulations, dosing



1: https://ahi.org/approval-and-regulation-of-animal-medicines/



Strategic Considerations – Innovative Food

- Patent claim strategy: Consumer-experience focused
 - · Food science approach
 - Functional claiming may not be as strong
- Cell-based meats: regulated by FDA and USDA Food Safety & Inspection Service (FSIS)
 - FDA oversees cell collection, coordinated oversight with FSIS for livestock and poultry, food products with cultured fish and seafood
 - FSIS & FDA: share oversight at harvest, principles for labeling, food safety
 - · FSIS: inspect manufacturing establishments and require all meet requirements, preapproval and verification of labels, enforcement actions, coordinate with FDA
- Plant-based: regulated by FDA
- Labeling FDCA (Federal Food, Drug, and Cosmetic Act): only animal derived foods can use words like "meat", "sausage" and "burger"

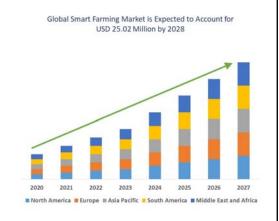






Strategic Considerations – Agribusiness/Digital Ag

- Growing market, relatively slow adoption
 - · Farmer reluctance
- Evolution in software patent eligibility: questionable older IP but Al/machine learning inventions protectable
- Protection of code (Google LLC v. Oracle America Inc., S. Ct. Apr. 5, 2021)¹
 - Using "small lines of code" is not infringement
- Blended approach to IP coverage
 - copyright, patent, trade secret, and trademark (brand)





Graph: https://www.databridgemarketresearch.com/reports/global-smart-farming-market 1: https://www.supremecourt.gov/opinions/20pdf/18-956_d18f.pdf 27

Summary

- AgTech is a growing and diverse field
- Different sectors within AgTech have different issues
- As in any other market, robust IP portfolios are critical in AgTech
- Regulatory strategy can also be a critical factor in product development



Questions?



Contact



Jennifer Giordano-Coltart

Kilpatrick Townsend & Stockton, LLP

919.420.1716 jgiordano-coltart@kilpatricktownsend.com



Megan Lyman

Owner
Lyman Consulting

919.259.6826



29

Locations

Counsel to innovative companies and brands around the world

We help leaders create, expand, and protect the value of their companies and most prized assets by bringing an equal balance of business acumen, technical skill, and creative thinking to the opportunities and challenges they face.



Anchorage Atlanta Augusta Beijing Charlotte Dallas Denver Houston Los Angeles New York Raleigh San Diego San Francisco Seattle Shanghai Silicon Valley Stockholm Tokyo Walnut Creek Washington DC Winston-Salem



www.kilpatricktownsend.com © 2021 Kilpatrick Townsend & Stockton LLP