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Innovation in Agricultural Technology: Strategic Considerations

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For:
Contra Costa County Bar Association
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Agriculture

10,000-year-old industry

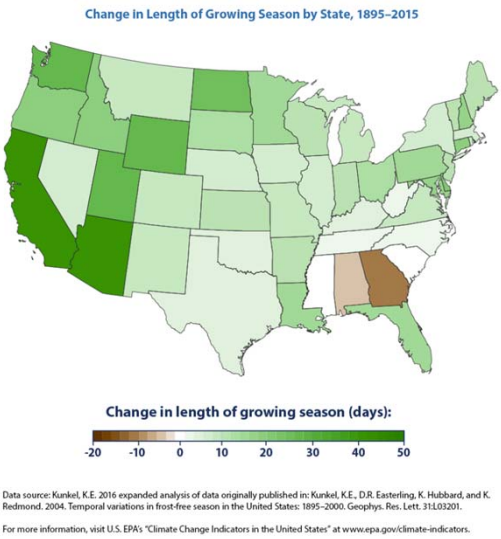
Feeding 10B people by 2050 (affects each of us ~3x a day)

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



AgTech v. Human Health

AgTech evolving following footsteps of Pharma

Similarities

- Consolidation
- Acquisition-based pipeline/External innovation
- Product development timeline/cost

Differences

- Less investment funds
- Diverse/larger syndicates
- Higher investor education barrier
- Investment amounts (~10x less)
- ROI (5-10x less)

AgTech: Select Sectors

Crop Protection | 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 use[1]
- Lack of innovation – majority of treatments were developed near WWII

Approaches

- Small molecules, nucleic acids, biologics, traits

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

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

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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

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

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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

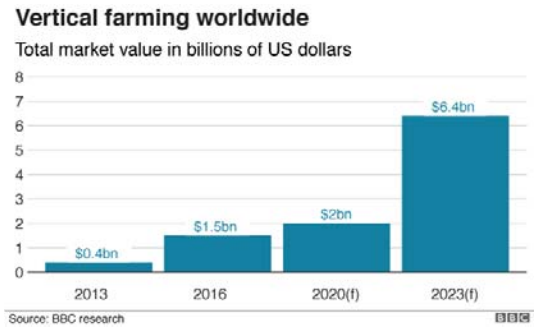


Photo Source: https://www.inc.com/jenna-broughton/bowery-snags-20m-to-fund-the-future-of-farming.html

Animal Health

Livestock, companion, equine

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

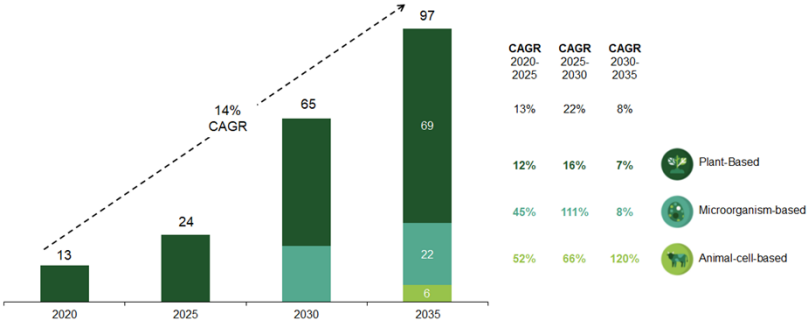
Approaches
- Small molecules, biologics, gene editing
- Vaccine development/deployment
- Health sensors – biometrics, mobility

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?ArticleID=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

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

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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

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

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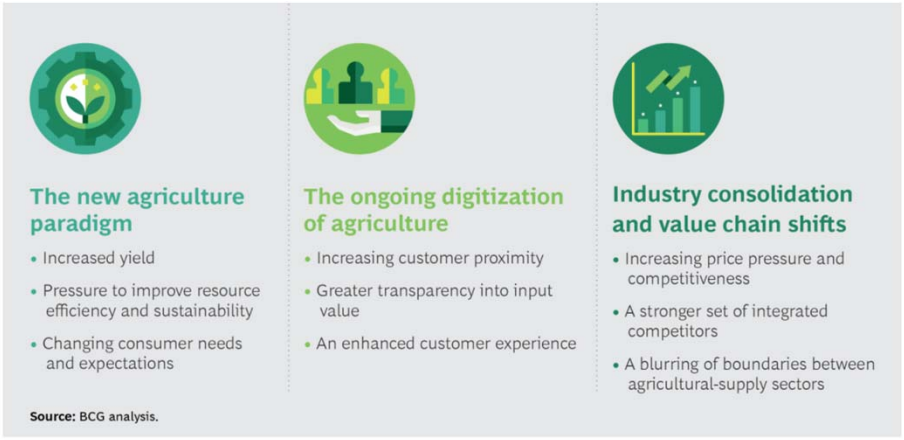
Three Forces are Disrupting the Agriculture Business Model



The new agriculture paradigm

- Increased yield
- Pressure to improve resource efficiency and sustainability
- Changing consumer needs and expectations

The ongoing digitization of agriculture

- Increasing customer proximity
- Greater transparency into input value
- An enhanced customer experience

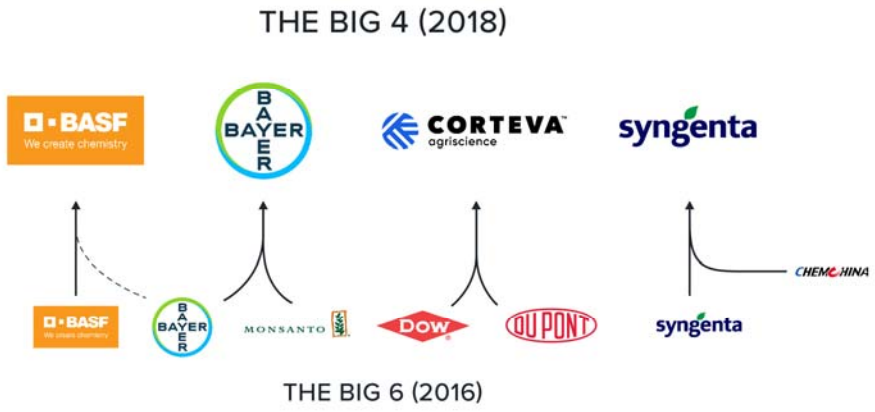
Industry consolidation and value chain shifts

- Increasing price pressure and competitiveness
- A stronger set of integrated competitors
- A blurring of boundaries between agricultural-supply sectors

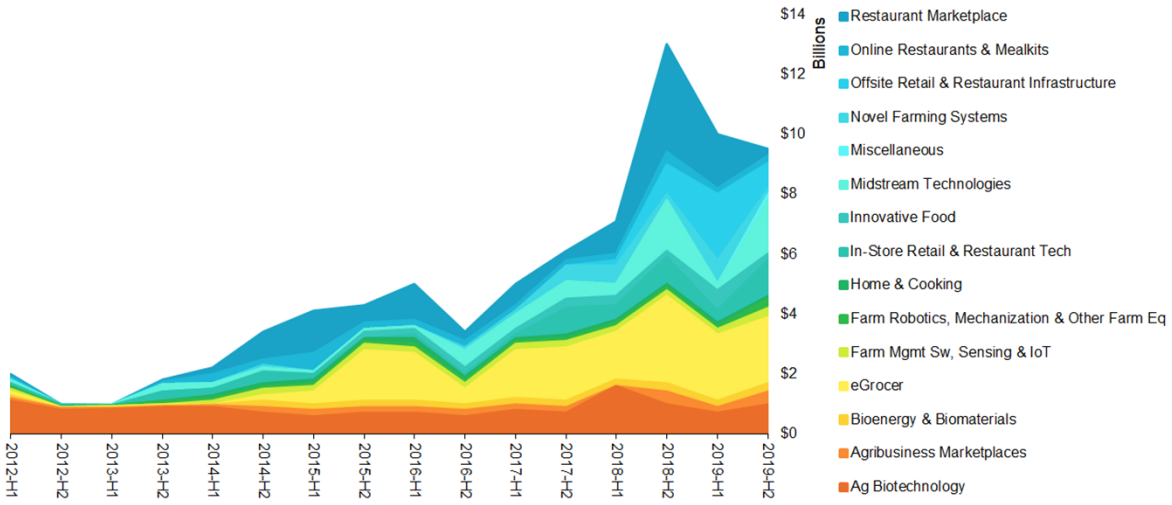
Source: BCG analysis.

Cite: https://www.bcg.com/publications/2018/growing-on-data-new-go-to-market-reality-agriculture

Consolidation of Ag



Deal Making in AgTech



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https://news.crunchbase.com/news/19-4b-invested-in-agri-foodtech-in-2019-according-to-agfunder/

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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

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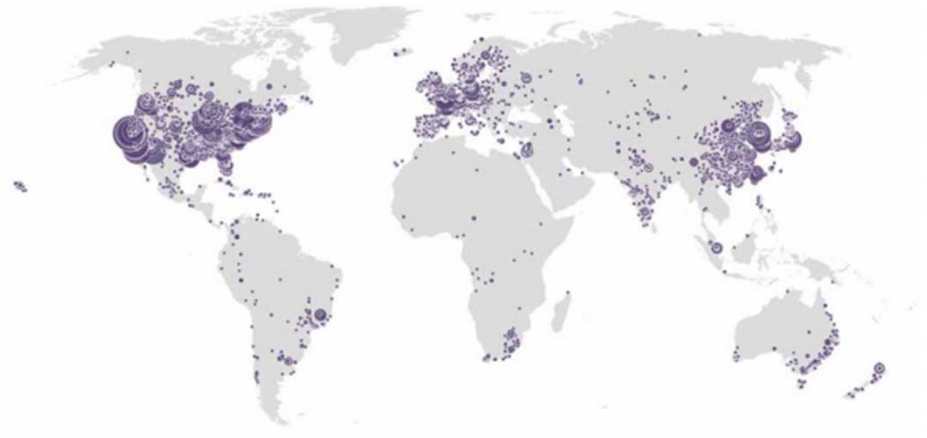
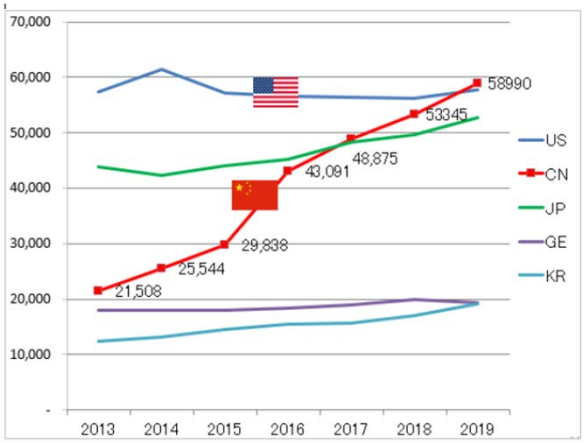
The distribution of agriculture biotech patent filings has been relatively wide since the 2000s



WIPO: China becomes top filer of PCT applications



GraphCite: https://www.lexology.com/library/detail.aspx?g=eed36553-8ef0-4009-ae04-4d9cd9305e0c

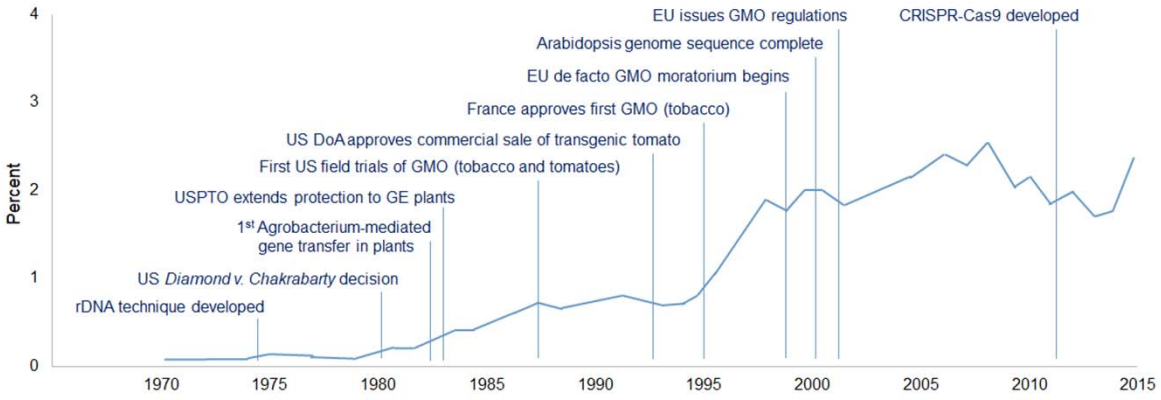
- 1.4B people: Agriculture is a national security interest
- China overall: has been the top patent filer for the last 2 years
- China's National Intellectual Property Agency has been issuing dispositions in favor of international IP rights (e.g., Bayer)[1]
- Trend in filing patent applications only in China (97% in last 5 year)[2]
- Incentives for filing
- 612K patents applied for between 2015-2019[2]

[1]: https://www.natlawreview.com/article/china-s-national-intellectual-property-administration-releases-top-ten-cases

[2]:https://www.chinadaily.com.cn/a/202011/21/WS5fb84c57a31024ad0ba95877.html#:~:text=Chinese%20institutes%20and%20enterprises%20applied,by%20the%20Chinese%20Academy%20of

Crop biotechnology growth

Share of Plant Biotechnology filing over total patent by origin (%)



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https://www.wipo.int/edocs/pubdocs/en/wipo_pub_944_2019-chapter4.pdf (modified From Fig. 4.6)

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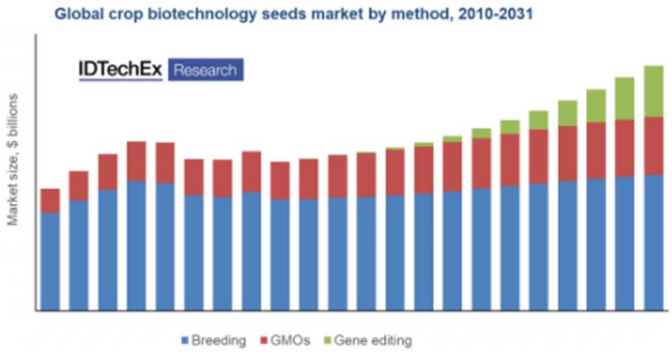
Strategic Considerations - Breeding/Editing

Crop Protection, Novel Farming Systems, Plant Fitness/Improvement

- GMO: $135M & ~10-20 years
- Gene Edited: $20M & ~2 years (may not be regulated)
- Breeding: $5-100M & 2-20 years
- 2020 SECURE Rule: regulation of edited crops – not regulated if *could* be found in nature OR have only one edit
- Directed epigenetic modification *not* regulated
- CRISPR: ownership rights in question, multiple licenses may be required
- EU: current ban on GMO & edited plants



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https://www.idtechex.com/en/research-report/genetic-engineering-in-agriculture-2021-2031/750

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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 non-cultivated), algae and macro-fungi (not bacteria) included
- Deposits required, not available in many jurisdictions

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 ingredient[1]:
  - 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

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

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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”

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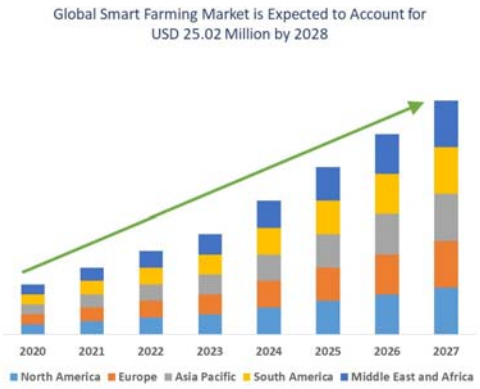
Strategic Considerations – Agribusiness/Digital Ag

- Growing market, relatively slow adoption
  - Farmer reluctance
- Evolution in software patent eligibility: questionable older IP but AI/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)



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Graph: https://www.databridgemarketresearch.com/reports/global-smart-farming-market

[1]: https://www.supremecourt.gov/opinions/20pdf/18-956_d18f.pdf

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?

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https://zinfandel.org/legendary-zinfandel-vineyards-of-the-contra-costa-county-ava/

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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.

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