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INTELLECTUAL PROPERTY FUNDAMENTALS & PATENT STRATEGIES

Patents – Key Basics

- Business tool
- The right to exclude
- Patent term
- Patent ownership as compared to licensed patents
- Patent filing and prosecution process
- Patent examination and patentability requirements (including "prior art")
- Third party patents (landscapes and diligence)

Patents are a business tool

- Patent strategy should align with business goals and business considerations
  - What is the fundamental business goal
  - Don’t let the patents drive the science

- Patents are one part of your IP tool box, but only one part:
  - Patents
  - Trademarks
  - Trade secrets
  - Copyrights

Patents are controlled by ownership or license

- Patent ownership originates with the inventors, or employers where a contract governing IP ownership exists
  - New companies: be sure employees, contractors, etc. have obligations to assign as part of employment agreement
  - University collaborations: be clear about IP and joint ownership issues from the start
    - AND … **where** the data is generated
- Patent rights (inherent in ownership) include:
  - Right to file patent applications
  - Right to prosecute
  - Right to enforce
  - Right to transfer
  - Right to license

Patent rights through license

- Licensees rights are set by contract
  - Provisions can allow for various levels of control and/or monetary obligations

- Key License Terms to Consider
  - Exclusive vs. non-exclusive
  - Field of use
  - Territory coverage
  - Right to enforce (generally for exclusive licensee)
  - Right to direct patent prosecution
  - Assignment or sublicensing of rights

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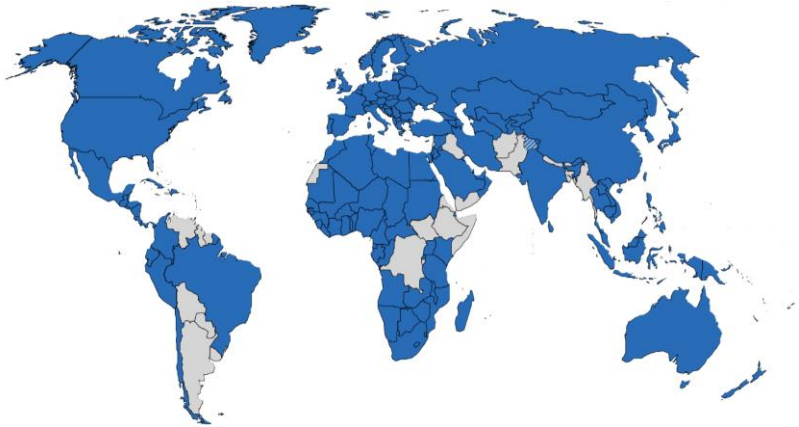
FILING PARTICULARS & STRATEGIES

Utility patents have a 20-year term

- Overall goal is to extend the period of patent exclusivity as long as possible!

- Tools to extend exclusivity period:
  - Rolling filings over the course of scientific/product development
  - Patent term extensions (due to delays in seeking product approval; PTE; one per product)
  - Patent term adjustments (US only, for USPTO delay; PTA; per patent)
  - Regulatory exclusivity provisions (many for orphan drugs)

- Where to file?
  - US
  - PCT (typical; most of world)
  - Investor interest ("trade bait")
  - Partner opportunities ("trade bait")



Exemplary Categories of Patent Protection

Composition of Matter	Formulation	Method of Making	Method of Use	Delivery Device
• Specific reference product (gene and protein sequences; compound) • Most readily discoverable and referenced patent	• The mixture the protein/compound is presented within • Various formulations, e.g., liquid, powder for reconstitution, etc.	• The process used to create the product • Specific to each individual manufacturer's process	• How the product is administered • Can be related to strength, indication, dosage schedule, administration type, etc.	• The delivery device for the product • Delivery devices are created to best administer the product and then patented as proprietary
				

Filing Process

(1) US provisional application(s) - initial filing dates(s)

- Not examined and does not start 20-year term

(2) PCT/non-provisional application - filed within 1 year (conversion deadline)

- Additional disclosures can be added during the 1 year period; 20-year term starts once filed
- Think about: novelty, non-obviousness, disclosure versus scope of protection (enablement and written description), patentable subject matter, double patenting

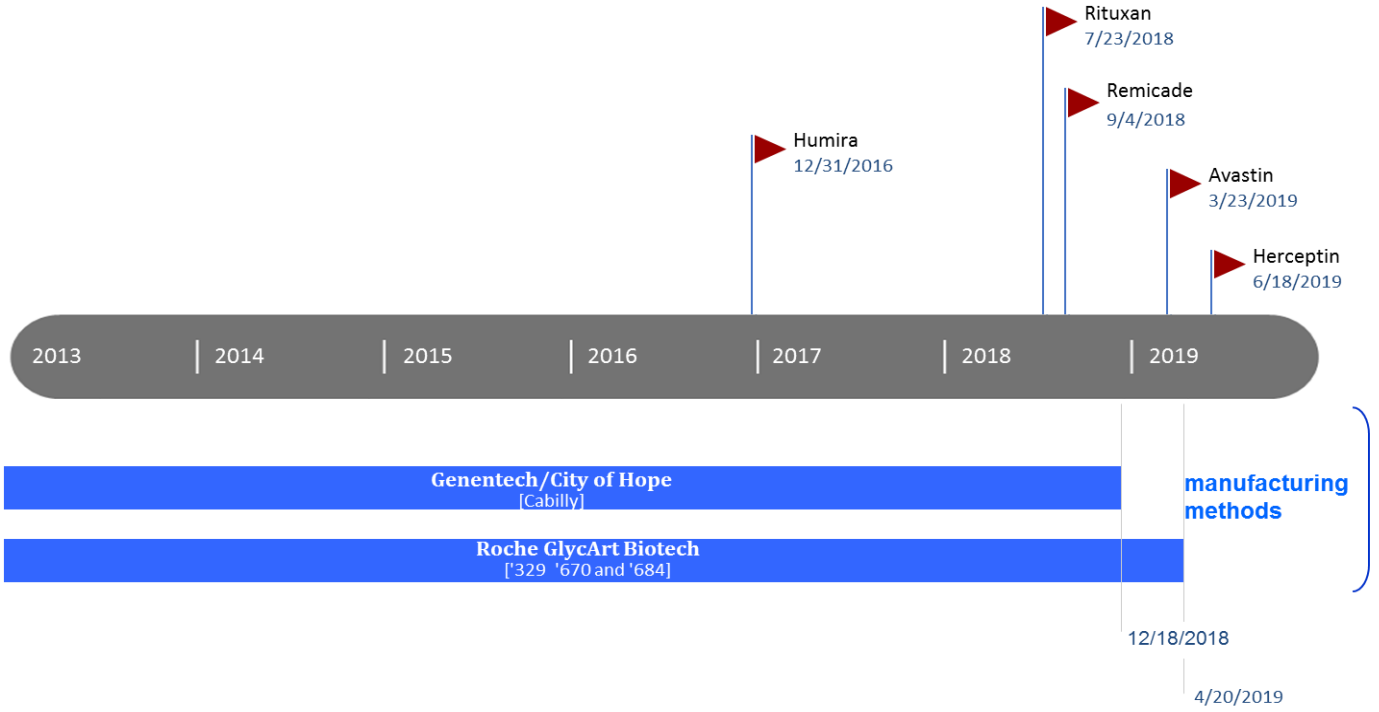
(3) At "30 months" from provisional filing date, file national stage applications (foreign and US if not filed)

Life Cycle Management (LCM)

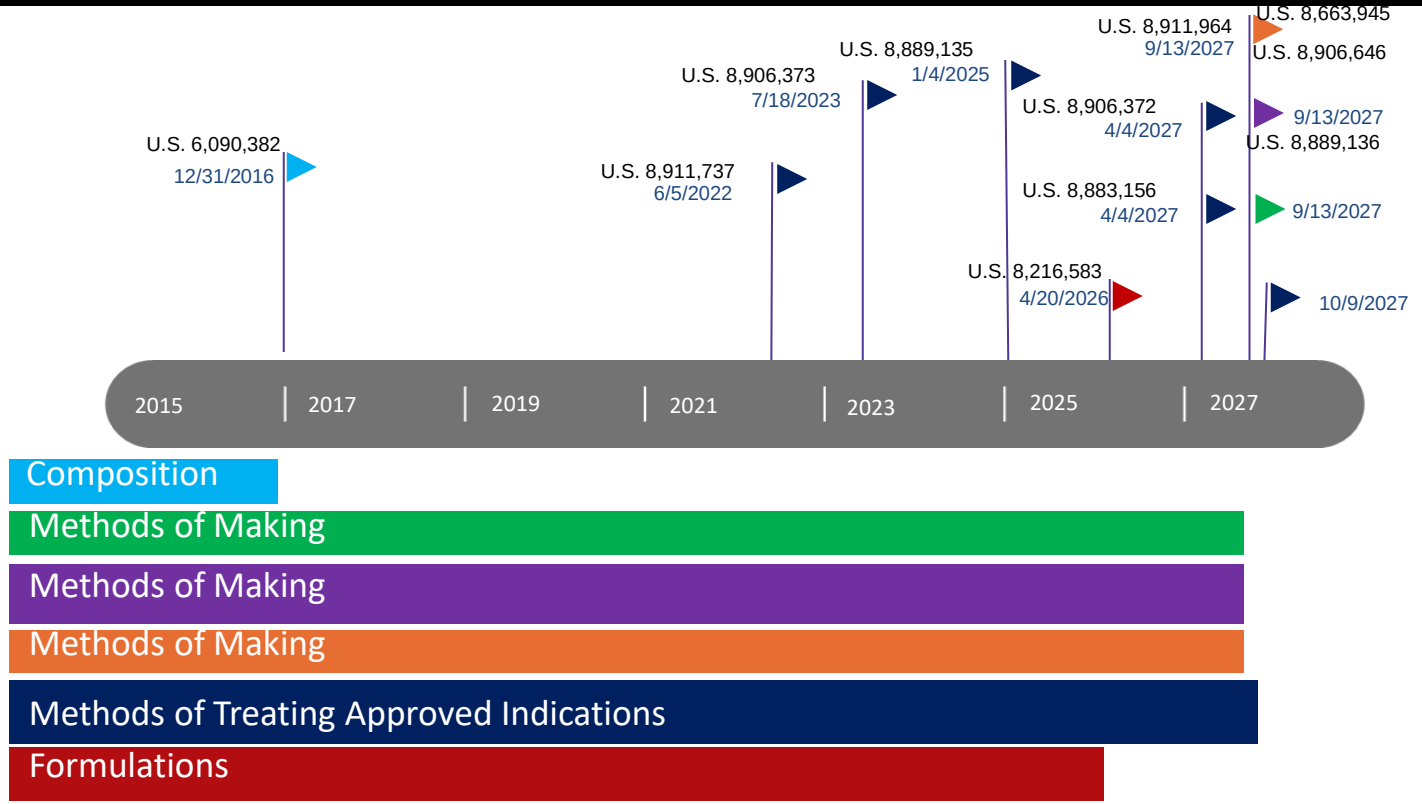
Goal of Patenting Biologics:
Extend Patent Exclusivity as long as possible

Early: "first generation" patents
Later: "life cycle management" patents

Composition of Matter Patent Expirations: "First Generation"



Key Humira Related Patent Expirations: "LCM"

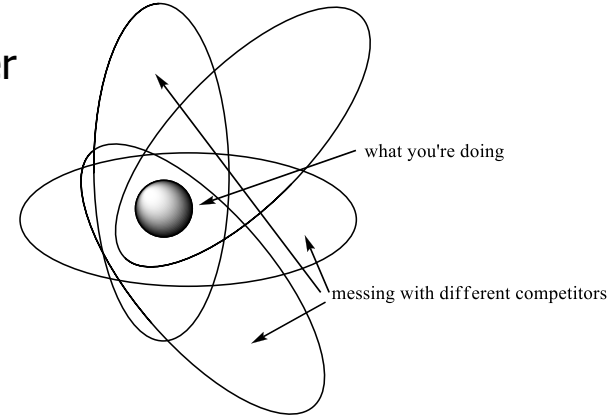


Labels and Patents

- Keytruda®: "Keytruda® is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors express PD-L1 as determined by an **FDA-approved test** with disease progression on or after platinum-containing chemotherapy"
- See list of approved Companion Diagnostics at FDA website
- These can be very specific:
  - For Keytruda®: "PD-L1 IHC 22C3 pharmDx is a qualitative immunohistochemical assay using Monoclonal Mouse Anti-PD-L1, Clone 22C3 intended for use in the detection of PD-L1 protein in formalin-fixed, paraffin-embedded (FFPE) non-small cell lung cancer (NSCLC) and gastric or gastroesophageal junction (GEJ) adenocarcinoma tissues using EnVision FLEX visualization system on Autostainer Link 48"
- Consider crafting claims around the analytical methods and subsequent treatment
  - "A method of detecting PD-L1 comprising . . . . And if level is [whatever the FDA says], administer Keytruda®"*
  - "A method of treating a patient following cisplatin therapy . . ."

Claiming Biologics: Take Home Messages

- Importance of LCM strategy mandates not disclosing too broadly in the first filings
- In both the U.S. and Europe, the law is changing
  - Defensible claims when issued might be difficult to enforce later
- Different types of claims and different filings to prepare for litigation
- Remember, goal is to have many patents that cover drug, its manufacture, formulation, and uses
- Abbvie's 60 patents to Humira forced Amgen settlement
- Stay up to date! Patent strategy should be informed by the science and the business strategy



(Or different country scopes)
(Or different claim scopes)
(Or different components)y

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RARE DISEASE STRATEGIES & REGULATORY FRAMEWORKS

US Strategy - Rare Disease Specifics

- Develop US patent strategy in line with regulatory approval
  - Market approval - think about PTE (only get PTE on one patent per approved drug)
  - US "Orphan Drug Act" can get up to 7-year market exclusivity from New Drug Application (5-year for "regular" drugs)
    - FDA cannot approve application using the same drug for the same orphan indication – does not preclude approval of drug using a different active moiety for same indication or same drug for a different indication
    - Can bar competitors from filing own NDA or BLA if seeking approval for same orphan indication (and does not show clinical superiority)
    - Lots of caveats – so be prepared in advance!

Foreign Strategy - Rare Disease Specifics

- Develop foreign patent strategy in line with regulatory approval
  - Foreign Jurisdictions:
    - Europe: “Orphan Drug Regulation” can allow for up to 10 year market exclusivity
    - Japan: “Orphan Drug Amendment” designation can allow for a 10-year extension of the period before a generic drug can enter the market for an orphan drug (7-years for orphan devices)
    - Singapore, Australia, Taiwan, South Korea, Canada all have orphan drug regulations as well
    - At least 35 countries have orphan drug related regulations
    - PTE in some foreign jurisdictions

PTE Summary

- Summary of countries with PTE:
  - US, Japan, EP (called Supplemental Protection Certificate, SPC) Australia, South Korea, Israel, Russia, Taiwan, Singapore, Canada (Certificate of Supplementary Protection, CPS), Ukraine (SPC)

- Summary of countries without PTE:
  - China, India, Brazil, Argentina, Mexico, New Zealand, Thailand, Indonesia

Regulatory Summary

	Drug	Biologic
Authorizing Statute/Regulations	FFDCA 21 C.F.R. 200s-300s	FFDCA & PHSA 21 C.F.R. 200s-300s, 600s, 1271
FDA Center	Center for Drug Evaluation and Research (CDER)	CDER or Center for Biologic Evaluation and Research (CBER)
Composition	Smaller, well-defined chemical structure, chemically synthesized	Complex mixtures, usually natural source
Manufacturing	May not need to be sterile ≈40-50 critical tests	Usually more complex, Usually requires aseptic processing Potential lot release ≈250+ critical tests
Application	New Drug Application (NDA) Safe and effective standard	Biologic License Application (BLA) Safe, pure, potent standard
Follow-On Products	Generic	Biosimilar
Innovator Exclusivity	3 years, 5 years	12 years
Publication	Orange Book	Purple Book

FDA Expedited Pathways

Program Type	Authority	Procedure	Disease Criteria	Qualifying Criteria	Development Benefit	Review Benefit	Post Approval
Accelerated Approval	21 C.F.R. 314 and 601. FFDCA 506(c)	Sponsor to raise during early development meetings with agency; no FDA mandatory response time	Serious or life-threatening disease or condition; unmet need	Provides meaningful benefit over available therapies and demonstrates effect through reasonably predictable surrogate endpoint or on an intermediate clinical end-point that can be measured earlier than irreversible morbidity or mortality	Modified clinical trial endpoints	n/a	FDA pre-submission of promotional materials; Phase IV confirmatory studies; expedited drug withdrawal process
Fast Track Designation	FFDCA 506(b)	As early as IND: • Sponsor requests designation • FDA grants (within 60 days) if criteria are met; ideally no later than pre-NDA / BLA • Can be rescinded	Serious or life-threatening disease or condition; unmet need	Non-clinical, clinical or other data showing potential to address unmet medical need, or QIPD; can apply to drug alone, or in combination	• Frequent FDA communication • Some approval timeline advantage if criteria met	Rolling review (Submit sections of NDA/BLA as complete)	None required • Can be withdrawn
Priority Review	CDER MAPP 6020.3; and PDUFA Goals	Sponsor requests prior to application submission. Upon receipt of application, agency makes recommendation and responds within 60 days; can apply to supplements	Serious condition	Significant improvement in safety or effectiveness in treatment, or treatment where no adequate therapy exists, pediatric supplement; QIPD; priority voucher drug	n/a	Expedited review (e.g., 6-8 months, compared to 10-12 months)	None required
Breakthrough Therapy Designation	FFDCA 506(a)	Any time before pre-NDA/BLA approval: • Sponsor requests designation • FDA grants within 60 days • Can be rescinded Note BT products may also get Priority Review if criteria are met	Serious or life-threatening disease or condition	Preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, or QIPD	- Intensive guidance on efficient development - Senior FDA Official Commitment - CMC flexibility - Significant R&D and approval timeline and advantage	Rolling review (submit sections of NDA/BLA as they are completed)	None required
Regenerative Medicine Advanced Therapies Designation	21st Century Cures Act, § 3033	Regenerative Medicine Advanced Therapies must have active IND FDA must provide a 60 day response	Serious or life-threatening disease or condition	Preliminary clinical evidence that drug has potential for addressing unmet need	Possible use of surrogate endpoints or intermediate clinical endpoints	Also eligible for accelerated approval or priority review if criteria are met	None

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FREEDOM-TO-OPERATE BASICS

Monitoring Others

- Reviewing third party patents and published applications to determine whether a product launch risks infringement
  - Identify third party patents and applications that create FTO "risk"
  - Review for non-infringement or invalidity positions
  - Safe harbor for clinical development stage

- "Patent landscaping" refers to the search and review of third party patents during the early stages of a program (identify crowded areas and troublesome IP)
  - Useful in differentiating similar technologies
  - Understand risks earlier, can help with development pathway
  - Highly recommend this at early stages of development (complement the science)

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CONCLUSIONS

Key Takeaways

- Understand your patent exclusivity position
  - Understand your patent coverage and gaps
  - Interplay between patents that cover drug and multiple indications versus exclusivity that may only cover one drug and one indication
- Evaluate pending provisional and PCT applications for needed improvement
- Manage the prior art early, by timing patent filings
- Understand the patent landscape (key third parties and their IP)
- Make sure IP licenses are industry friendly
- Make sure to set-up IP for maximizing orphan disease regulatory benefits
- Understand the regulatory framework that matches your business strategy


QUESTIONS/COMMENTS?
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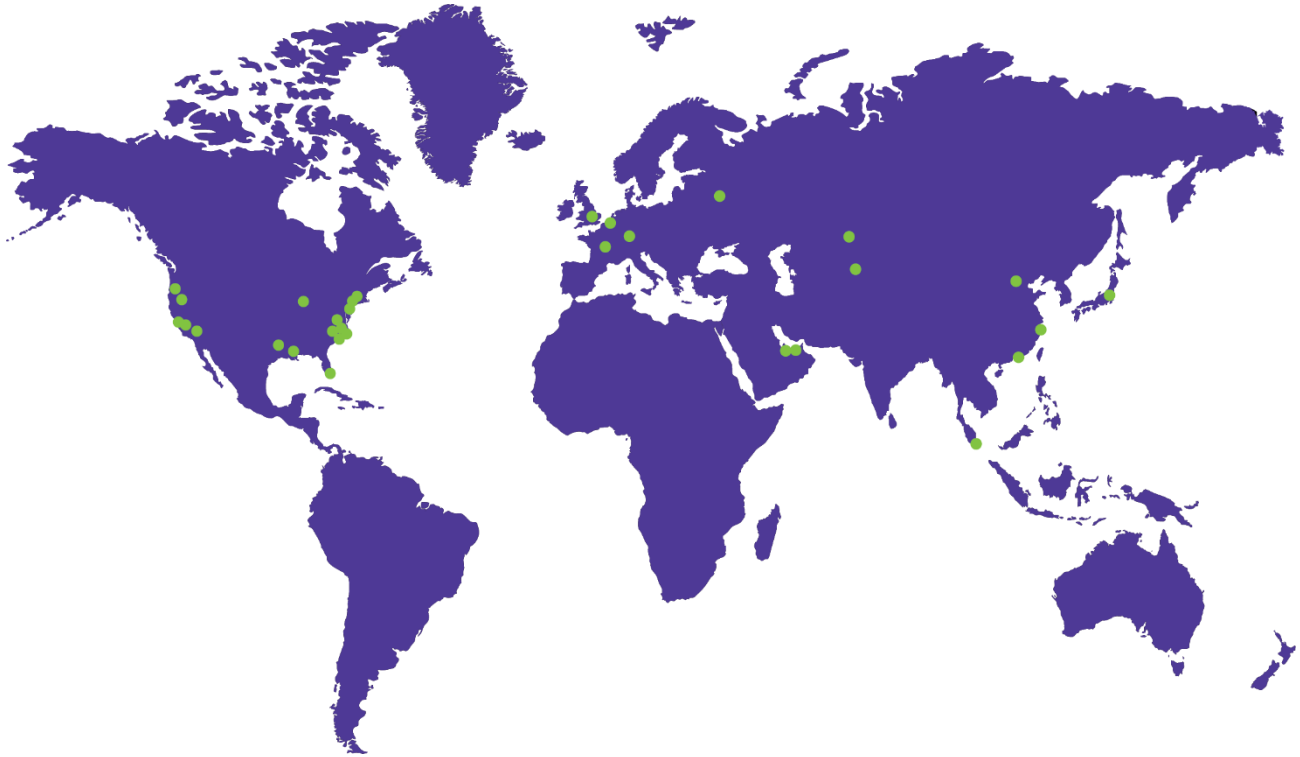
Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Abu Dhabi
Almaty
Beijing*
Boston
Brussels
Century City
Chicago
Dallas
Dubai
Frankfurt
Hartford
Hong Kong*
Houston
London
Los Angeles
Miami
New York
Nur-Sultan
Orange County
Paris
Philadelphia
Pittsburgh
Princeton
San Francisco
Shanghai*
Silicon Valley
Singapore*
Tokyo
Washington, DC
Wilmington



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