Defining the Threshold of What Should Be Patented
• New forms of innovation have challenged what kinds of inventions can be patented
  o Changes to subject matter eligibility have limited what can be patented

• Denying patents to these new forms of innovation will reduce old and new inventions brought to the marketplace

• Predictability matters
• Purpose of Patent Doctrines
• Subject matter eligibility in the U.S. and Europe
• Examples from recent high-tech cases
• Examples from recent biotech cases
• Examining hypothetical inventions for what should be the threshold for IP rights
Purpose of Patent Doctrines
• Copyright allows creators to profit from their works
  o Length of right based on author, affirmative rights to use

• Trademarks encourage protection of distinctive marks to allow consumers to determine source
  o Maintenance of right generally based on use

• Patents incentivize creation and disclosure of useful inventions
  o Term based on disclosure, validity determined by reference to prior art
TWO KEY RATIONALES FOR PATENT RIGHTS

• Exclusivity incentivizes R&D for useful inventions
  o The value of the patent term encourages inventors to create *improvements* of prior technologies

• Quid pro quo exchange of defined exclusivity for disclosure
THREE CORE PATENT REQUIREMENTS

• Patent eligibility
  o Is this the kind of thing that should be patentable?

• Inventiveness
  o Is the difference from the prior art enough?

• Disclosure
  o Is the public getting the benefit of its bargain?
PATENT ELIGIBILITY

- Threshold question – Is the invention within the scope of patentable subject matter

- Is it within a legally defined category?
- Is it useful?
- Is it new?
- Is it otherwise excluded?
• It is odd that a threshold question to bring inventions within the scope of patent laws has detailed exceptions
  o There are even exceptions to the exceptions

• In the U.S. these exceptions are:
  o Abstract ideas
  o Laws of nature
  o Natural phenomenon

• Elsewhere, exceptions include methods of medical treatment
Despite the seeming order of the core patent requirements...
Is there a good reason to have specific exceptions to patentability?
Subject matter eligibility in the U.S. and Europe
The goal of a **threshold question** is to determine whether the invention is the kind of thing that should be patented.

• Is it within the textually defined class?
  - U.S. – “process, machine, manufacture, or composition of matter, etc.”
  - EPO – “any inventions, in all fields of technology”

• Is it within an exception?

• Is there something that saves an invention within an exception? (U.S. Only)
In the U.S., the last two questions are the Mayo/Alice test
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- Step 1 – Is the claim directed to an exception (abstract idea, law of nature, natural phenomenon)?
- Step 2 – Does the claim contain something more (inventiveness) to rescue the claim?
Four recent Supreme Court cases establish the current framework:

- *Bilski v. Kappos* – Method of hedging trading risk is an abstract idea
- *Mayo v. Prometheus* – Method of determining drug metabolism is a natural phenomenon
- *Myriad v. AMP* – Isolated DNA is a product of nature, cDNA is not
- *Alice v. CLS Bank* – Computer method of mitigating settlement risk is an abstract idea
• How to determine what a claim is “directed to”

“A method of exchanging obligations as between parties, each party holding a credit record and a debit record with an exchange institution, the credit records and debit records for exchange of predetermined obligations, the method comprising the steps of:

“(a) creating a shadow credit record and a shadow debit record for each stakeholder party to be held independently by a supervisory institution from the exchange institutions;

“(b) obtaining from each exchange institution a start-of-day balance for each shadow credit record and shadow debit record;

“(c) for every transaction resulting in an exchange obligation, the supervisory institution adjusting each respective party’s shadow credit record or shadow debit record, allowing only these transactions that do not result in the value of the shadow debit record being less than the value of the shadow credit record at any time, each said adjustment taking place in chronological order, and

“(d) at the end-of-day, the supervisory institution instructing on[e] of the exchange institutions to exchange credits or debits to the credit record and debit record of the respective parties in accordance with the adjustments of the said permitted transactions, the credits and debits being irrevocable, time invariant obligations placed on the exchange institutions.” App. 383–384.

Alice v. CLS Bank
U.S. – LACK OF CLARITY

• How to determine whether a claim directed to an exception claims “something more” or an “inventive concept”

• Are there ways that this is different than non-obviousness (inventive step)?
The EPC has a similar list of exceptions

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
(a) discoveries, scientific theories and mathematical methods;
(b) aesthetic creations;
(c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
(d) presentations of information.
• But the EPC limits the exceptions only to the exceptions “as such”
V. Claim 1 of the main request reads:

"An automatic auction method executed in a server computer comprising the steps of:
a) transmitting information on a product to be auctioned to a plurality of client computers via a network, each client computer belonging to a bidder;
b) receiving a plurality of auction ordering information pieces, each including a desired price and a maximum price in competitive state, for purchase of said product, from the plurality of client computers via the network;
c) storing the received auction ordering information pieces in the server computer for respective bidders;
d) setting an auction price;
e) determining whether there is any bidder who proposes a desired price equal to or higher than the auction price using the auction ordering information pieces stored in the server computer;
f) if there is no bidder in the step e), lowering the auction price, and repeating the step e);
g) if there is more than one bidder at step e), judging whether there is more than one bidder for whom the auction price is less than or equal to the desired price such that a competitive state occurs using the auction ordering information pieces stored in the server computer;
h) if the competitive state occurs, increasing the auction price by a predetermined value;
i) excluding the bidder who proposes acceptable a price lower than the increased auction price and specifying the other bidder or bidders using the auction ordering information;
j) judging whether the competitive state occurs among the bidder or bidders specified in the step i);
k) repeating the steps h), i) and j) and determining the remaining bidder as a successful bidder when there is no competitive state at step j); and
l) if no competitive state occurs in the step g), determining the remaining bidder as a successful bidder."
Quick TRIPS background

- TRIPS contains a non-discrimination principle, that generally prohibits having special patent rules for different technologies Art 27(1)
- However, TRIPS has an exception to the non-discrimination provision, allowing the exclusion of “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” Art. 27(3)(a)

Many countries use this to prohibit methods of medical treatment
EPC’S PHARMA RESTRICTION

• Much like the other EPC restrictions, the rule is in place but limited

• Proper claim drafting can avoid this restriction, but may have impacts on who is an infringer and scope of the claim

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.
• Exceptions to eligibility are common, but function in two widely disparate ways

• U.S. – Restricts claims directed to the exceptions, but meaning of “directed to” and the role of additional claim limitations still unclear

• EPC – Only restricts claims that are directed to exceptions “as such”
DISCUSSION PAUSE

Are there meaningful policy goals for these exceptions?

Can (or do) the exceptions accomplish meaningful policy goals?

How else could these be achieved?
Examples from Recent High-Tech Cases
• Animated lip-sync automation

A method for automatically animating lip synchronization and facial expression of three-dimensional characters comprising:

obtaining a first set of rules that define output morph weight set stream as a function of phoneme sequence and time of said phoneme sequence;

obtaining a timed data file of phonemes having a plurality of sub-sequences;

generating an intermediate stream of output morph weight sets and a plurality of transition parameters between two adjacent morph weight sets by evaluating said plurality of sub-sequences against said first set of rules;

generating a final stream of output morph weight sets at a desired frame rate from said intermediate stream of output morph weight sets and said plurality of transition parameters; and

applying said final stream of output morph weight sets to a sequence of animated characters to produce lip synchronization and facial expression control of said animated characters.
• Improvements to a database/spreadsheet

A data storage and retrieval system for a computer memory, comprising:

means for configuring said memory according to a logical table, said logical table including:

a plurality of logical rows, each said logical row including an object identification number (OID) to identify each said logical row, each said logical row corresponding to a record of information;

a plurality of logical columns intersecting said plurality of logical rows to define a plurality of logical cells, each said logical column including an OID to identify each said logical column; and

means for indexing data stored in said table.

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Analysis of information from an electric grid

12. A method of detecting events on an interconnected electric power grid in real time over a wide area and automatically analyzing the events on the interconnected electric power grid, the method comprising:

- receiving a plurality of data streams stamped synchronously wherein the measurements are collected at real-time points over the electric power grid at least two electrical transmission substations, transmitting reliability coordination signals; receiving data from a plurality of sources;
- detecting and analyzing even the plurality of data streams based on at least one of the following, and rates of change for one or more measurements from the data streams: stability metrics derived from measurements from the data streams, oscillation modes, derived stability metrics; and
- displaying the event analysis results and diagnoses of events and associated ones of the metrics from different categories of data and the derived metrics in visuals, tables, charts, or combinations thereof, the data comprising at least one of monitoring data, tracking data, historical data, prediction data, and summary data;
- displaying concurrent visualization of measurements from the data streams and the dynamic stability metrics directed to the wide area of the interconnected electric power grid;
- accumulating and updating the measurements from the data streams and the dynamic stability metrics, grid data, and non-grid data in real time as to wide area and local area portions of the interconnected electric power grid; and
- deriving a composite indicator of reliability that is an indicator of power grid vulnerability and is derived from a combination of one or more real-time measurements or computations of measurements from the data streams and the dynamic stability metrics covering the wide area as well as non-power grid data received from the non-grid data source.
• Analysis of information from an electric grid

tent-eligible applications. The claims at issue do not require any nonconventional computer, network, or display components, or even a “non-conventional and non-generic arrangement of known, conventional pieces,” but merely call for performance of the claimed information collection, analysis, and display functions “on a set of generic computer components” and display devices.

• This means that the court found all that language in the claim to be generic
What general points can be learned from the examples?
Examples from Recent Biotech Cases
Freezing hepatocytes

1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:

   (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from non-viable hepatocytes,

   (B) recovering the separated viable hepatocytes, and

   (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.
• Embryo gene detection

1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises

   amplifying a paternally inherited nucleic acid from the serum or plasma sample and

   detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.
Examining hypothetical inventions for what should be the threshold for obtaining patent rights
• Each case can be analyzed using the doctrines (and we will)...

• BUT, it is more important to think about whether that kind of claim should be eligible for policy reasons
Claim: A system for improving performance of a mobile device comprising:
1) a memory with instructions
2) the instructions being a program for reducing the number of computer cycles used to display an image
3) wherein said system is capable of extending battery life
Claim: A method for improving a graphic user interface (GUI) comprising
identifying multiple areas of interest for a user
identifying whether those areas are predominantly horizontal or vertical
arranging the areas of interest horizontally if horizontal and vertically if vertical
highlighting an active region of input
updating the arrangement as new areas of interest are identified
1. A method for displaying market information relating to and facilitating trading of a commodity being traded in an electronic exchange having an inside market with a highest bid price and a lowest ask price on a graphical user interface, the method comprising:

dynamically displaying a first indicator in one of a plurality of locations in a bid display region, each location in the bid display region corresponding to a price level along a common static price axis, the first indicator representing quantity associated with at least one order to buy the commodity at the highest bid price currently available in the market;

dynamically displaying a second indicator in one of a plurality of locations in an ask display region, each location in the ask display region corresponding to a price level along the common static price axis, the second indicator representing quantity associated with at least one order to sell the commodity at the lowest ask price currently available in the market;

displaying the bid and ask display regions in relation to fixed price levels positioned along the common static price axis such that when the inside market changes, the price levels along the common static price axis do not move and at least one of the first and second indicators moves in the bid or ask display regions relative to the common static price axis;

displaying an order entry region comprising a plurality of locations for receiving commands to send trade orders, each location corresponding to a price level along the common static price axis; and

in response to a selection of a particular location of the order entry region by a single action of a user input device, setting a plurality of parameters for a trade order relating to the commodity and sending the trade order to the electronic exchange.
• Claim: Molecule X

• Molecule X was discovered in nature but can treat Parkinson’s disease
• Claim: A pharmaceutical composition comprising Molecule X and inert ingredients

• Molecule X was discovered in nature but can treat Parkinson’s disease
• Claim: A method of treating parkinson’s disease, comprising administering a therapeutically effective dose of molecule X

• Molecule X was discovered in nature but can treat parkinson’s disease

• Does the analysis change if instead, it is molecule Z, which was synthesized in a lab?
• Claim: Molecule X for use in the treatment of Parkinson’s

• Molecule X was discovered in nature but can treat Parkinson’s disease

• Does the analysis change if instead, it is molecule Z, which was synthesized in a lab?
• Claim: Molecule X for use in the treatment of gout

• The ability of molecule X to treat gout was discovered after the publication of molecule X for parkinson’s
• Claim: A method for treating cancer comprising
   identifying whether a patient has a genotype of H1 or H2
   if the patient has genotype H1,
   administering molecule X
   if the patient has genotype H2,
   administering molecule Z.
• Claim: A method of diagnosing a patient with a myasthenic disorder comprising obtaining a blood sample determining the ratio of molecules Ch to ACh if the ration of Ch to ACh is less than 1, identifying the patient as having a myasthenic disorder
• Claim: A method of treating a patient with a myasthenic disorder comprising obtaining a blood sample determining the ratio of molecules Ch to ACh if the ratio of Ch to ACh is less than 1, identifying the patient as having a myasthenic disorder if the patient has a myasthenic disorder, administering a compound to treat the myasthenia
A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:

determining whether the patient is a CYP2D6 poor metabolizer by:

obtaining or having obtained a biological sample from the patient;

and

performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and

if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and

if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,

wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.
CONCLUSIONS

• A threshold test for patent eligibility is useful
  o Allows broader IP system to function efficiently

• Exceptions to eligibility pose a potential danger to a well-functioning patent system
  o Increase unpredictability
  o Blur policy and doctrinal lines
  o Invoke less developed policy rationales
Thank You