Finding a Solution to the § 101 Puzzle

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Overview

- Roundtable Federal Register questions 7-13
- Roundtable Federal Register questions 3-6

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Fed. Reg. Questions 7-13

- Please review exhaustive comments by Coalition for 21st Century Medicine on earlier guidance
  - https://www.uspto.gov/sites/default/files/patents/law/comments/mm-a-coalitionfor21stcenturymed20140806.pdf
  - https://www.uspto.gov/sites/default/files/documents/2014ig_a_21st_2015mar16.pdf

Fed. Reg. Questions 7-13

- Coalition comments provide…
  - Practical approach to **preemption** (Fed. Reg. question 7)
  - Insight on harmonizing and faithfully (yet narrowly) interpreting and applying key cases to **life science inventions** (Fed. Reg. questions 8-13)
  - Extensive examples with detailed analysis
  - Help in fleshing out ideas on later slides (*e.g.*, "discrete natural unit")

Fed. Reg. Questions 3-6

- Strong evidence of a § 101 problem
- Empassioned commentary at November 2016 Roundtable in Alexandria
- CAFC denial of *en banc* rehearing in *Sequenom*
- *Amicus* briefs in recent court cases
- Patent protection for ground-breaking innovations (*e.g.*, NIPT) swept away
- Companies responding to changed landscape
  - Not pursuing some technologies
  - Electing different types of protection (trade secret)

What Is the Root of the Problem?

- Exceptions to eligibility are entirely judicially-created
- No basis in (contrary to?) the statute
  - Statutory language gives no hint of any exception
- No basis in (contrary to?) Constitution
  - SCOTUS has never cited Constitution as basis for the exceptions

Constitutional Issues? No.

- ***Bergy***: "*The **only** restraints placed on Congress pertained to the means by which it could promote useful arts, namely, through […] securing 'exclusive rights' […]. The conditions to be imposed on the granting of such rights[…] were left to Congress to devise*."

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Potential Fixes

- Judicial solution?
  - SCOTUS created (*e.g.*, *Mayo*, *Myriad*) and has refused to fix (*e.g.*, *Sequenom*) the problem
  - CAFC improving (*e.g.*, *McRO*), but bound by SCOTUS decisions (*e.g.*, *Sequenom*)
- Agency solution?
  - Examination guidance = Opportunity to shape interpretation of new cases, but…
  - PTO bound by both SCOTUS and CAFC

Legislative Solution

- Precedent: Congress "corrected" SCOTUS *Deep South* decision
- USPTO's role: Expert agency that can be influential in shaping legislation
- How do you fix a statute that's not broken?
  - Not a problem of courts misconstruing statutory language
  - § 101 already says "***any*** *… invention or discovery*" is patentable

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Legislative Solution

- Many proposals being discussed
- Wholesale elimination of judicial exclusions (Fed. Reg. question 3)
  - Less preferred
- Enumerate specific statutory exceptions (Fed. Reg. questions 4-6)
  - More preferred

Wholesale Elimination of Exclusions (Fed. Reg. Question 3)

- Relatively simple to draft…
  - Expressly state there are no exceptions to patent eligibility; expressly state that natural laws, etc. are eligible for patenting
  - Fewer unintended consequences
- But not the best approach
  - People have become accustomed to the exceptions (visceral reaction)
  - Expressly saying a law of nature can be patented simply may not be palatable anymore

Enumerate Specific Statutory Exceptions (Fed. Reg. Questions 4-6)

- More complicated to draft…
  - Which exclusions get codified?
    - Building a coalition v. pet issues
  - Unintended consequences
- But ultimately the better solution
  - Brings clarity and predictability
  - Moves beyond whole-cloth judicial creations, emotional rhetoric and arbitrary values of individual judges

Learn from European Approach

- International harmonization has been a recurrent theme in § 101 *amicus* briefs
- European practitioners widely perplexed by § 101 developments in US
- EPC approach seen as rational, balanced and fair

Learn from European Approach

- Everything is eligible by default
- Exclusions are specifically listed in EPC
  - List is expressly not exhaustive
- Excludes a lot
  - Games
  - Software
  - Mental acts
  - Others

"Americanize" It

- Everything is eligible by default
  - Text of § 101 stays mostly the same, but…
- Create new statutory sub-section specifically and exhaustively listing categories of excluded matter

  35 U.S.C. § 101(a): "*Inventions Patentable. Except for subject matter expressly excluded by sub-section 101(c) of this title, and subject to the requirements of sub-section 101(b) and sections 102, 103 and 112 of this title, whoever invents or discovers any subject matter, including but not limited to any process, machine, manufacture, or composition of matter, or any improvement thereof, may obtain a patent therefor.*"

“Americanize” It

- New sub-section 101(b) can codify the current utility requirement
  - No more judicial creations; **<u>everything</u>** is statutory
- New sub-section 101(c) can flexibly exclude anything Congress chooses
  - Current judicial exceptions codified, but now carefully and precisely redefined
  - “Ethical” exclusions
  - Anything else

Finally Bring Clarity to Judicial Exceptions

- 35 U.S.C. § 101(c): "*Excluded Subject Matter. A patent may not be issued on any application in which any functional embodiment of any claim is any of the following* per se*:* […]*.*"

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Finally Bring Clarity to Judicial Exceptions

- *"(i) any process in which every step can be readily performed by an unaided human mind of average intelligence;*
- *(ii) a statement of a direct, natural cause and effect relationship;*
- *(iii) any event or process acting solely according to or under the influence of any subject matter in (ii), unaltered by human activity;* […]"

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Finally Bring Clarity to Judicial Exceptions

- "*(iv) any undivided element, mineral or organism entirely unmodified from its intact natural state;*
- *(v) a discrete, natural unit of any subject matter in (iii) whose function is unaltered from its natural state; […]*"

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Framework to Incorporate Other Exceptions

- "*(vi) an entire human organism, any portion thereof comprising any portion of a central nervous system, or processes for producing either;*
- *(vii) any process for modifying the germ-line genetic make-up of any human organism;*
- *(viii) any process for modifying the genetic make-up of any non-human animal wherein such modification is likely to cause such animal suffering without any substantial medical benefit to man or animal; or*
- *(ix) any product or process relating to the use of any embryo comprising a human cell for industrial or commercial purposes;*
- *(x)* [surgical procedures as defined in § 287(c)]*;*
- Others…

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Conclusions

- Previous comments (Coalition's and others') outline detailed, insightful approaches to life science inventions
- Best legislative approach follows European lead of codifying a list of specific exclusions
- USPTO is playing and will continue to play an important role in finding a solution

Thank You

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