



# Practitioners' Perspective on 101 as Applied to Biotech Applications

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# Overview

- Goals
- Methodology
- Data related to office actions
  - Prevalence of 101 rejections
  - Prosecution outcomes
- Data related to appeals
- Conclusions

# Methodology

# Methodology – Changing 101 Landscape

- *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. \_\_\_, 132 S.Ct. 1289 (2012).
  - Interim Laws-of-Nature Guidelines
- *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. \_\_\_, 133 S.Ct. 2107 (2013).
  - Guidelines Responsive to Myriad and Mayo
- *Alice Corp. v. CLS Bank Int’l*, 134 S.Ct. 2347 (2014).
  - Preliminary Guidelines Responsive to Alice
- *BRCA1 & BRCA2-Based Hereditary Cancer Test Patent Litigation v. Ambry Genetics Corp.*, 774 F.3d 755 (Fed. Cir. 2014).
  - Interim Guidelines
- *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, \_\_\_ F.3d \_\_\_ (Fed. Cir. 2015).
  - July 2015 Update: Subject Matter Eligibility (waiting on Nature Examples)

# Methodology

- Selection of Relevant Time Periods

	SCOTUS Decisions	USPTO Guidelines	Our Data-Set Time Periods
<b>January 2012</b>			"Pre-Mayo" data set
<b>March 2012</b>	<i>Mayo Collaborative Svs. V. Prometheus Labs.</i>		
<b>July 2012</b>		Interim Laws-of-Nature Guidelines	
<b>October 2012</b>			"After Mayo" data set
<b>June 2013</b>	<i>Ass'n for Molecular Pathology v. Myriad Genetics</i>		
<b>August 2013</b>			"After Myriad" data set
<b>March 2014</b>		Guidelines responsive to Myriad and Mayo	
<b>May 2014</b>			"After Myriad Guidelines" data set
<b>June 2014</b>	<i>Alice Corp. v. CLS Bank International</i>		
<b>June 2014</b>		Preliminary Guidelines responsive to Alice	
<b>July 2014</b>			"After Alice" data set
<b>December 2014</b>		Interim Guidelines	
<b>February 2015</b>			"After Interim Guidelines" data set

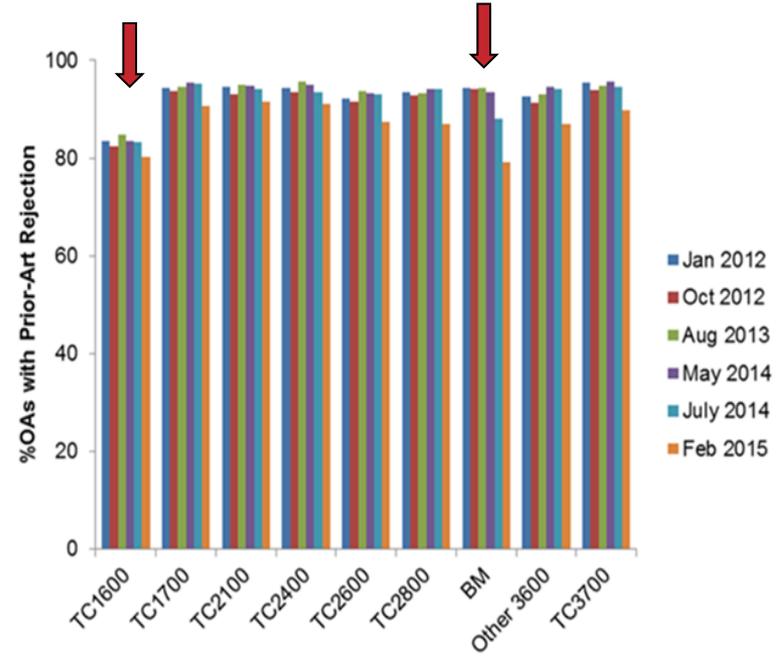
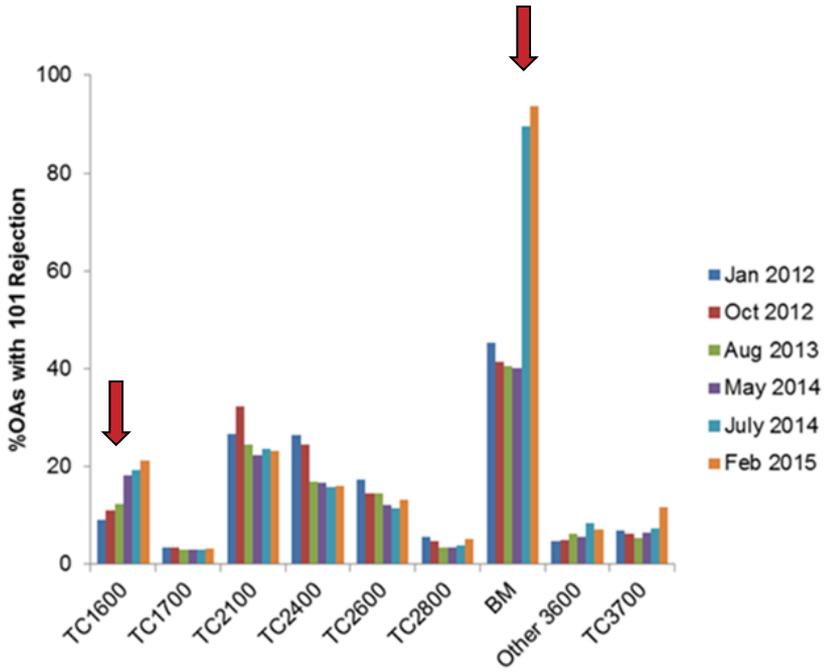
# Methodology

- LexisNexis PatentAdvisor<sup>®</sup>
- Identification of all USPTO actions issued between 14<sup>th</sup> and 28<sup>th</sup> of identified month
- Determination of action: Allowance/Rejection
- Analyze 101 rejections across TC1600 Art Unit Groups

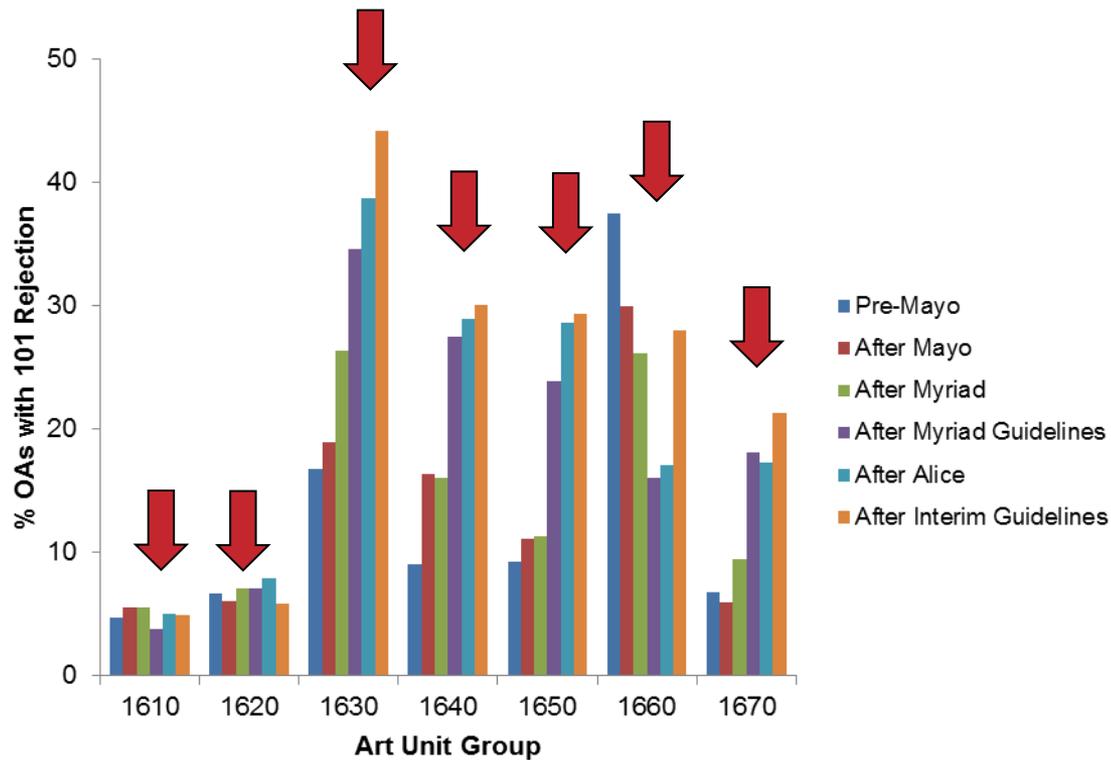
AU Group	Technology
1610	Organic Compounds: Bio-Affecting, Body Treating, Drug Delivery, Steroids, Herbicides, Pesticides, Cosmetics, and Drugs
1620	Organic Chemistry
1630	Molecular Biology, Bioinformatics, Nucleic Acids, Recombinant DNA and RNA, Gene Regulation, Nucleic Acid Amplification, Animals and Recombinant Plants, Combinatorial/Computational Chemistry
1640	Immunology, Receptor/Ligands, Cytokines, Recombinant Hormones, and Molecular Biology Thereof
1650	Fermentation, Microbiology, Isolated and Recombinant Proteins/Enzymes
1660	Plants
1670	Cross-section of TC1600 subject matter uniting technology from the organic, nucleic acid, protein, and antibody arts, with a general focus on the pharmacological, diagnostic, and therapeutic aspects

# Prevalence of 101 rejections

# Prevalence of 101 rejections across Technology Centers

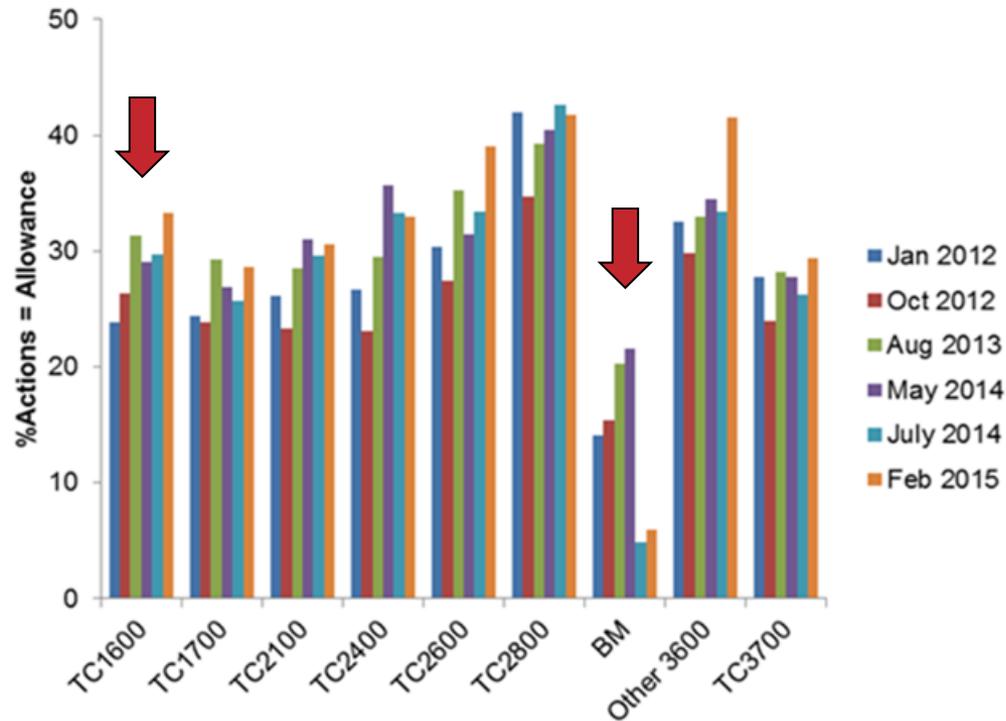


# Prevalence of 101 rejections across 1600 art unit groups

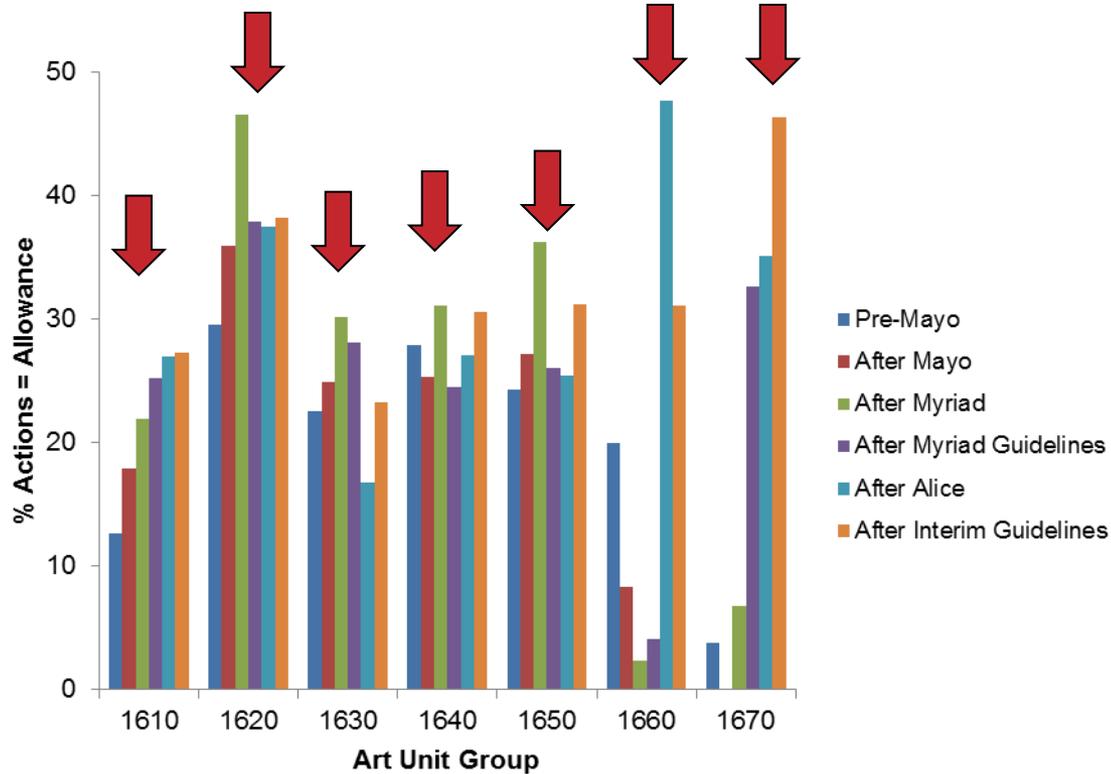


# Prosecution Outcomes

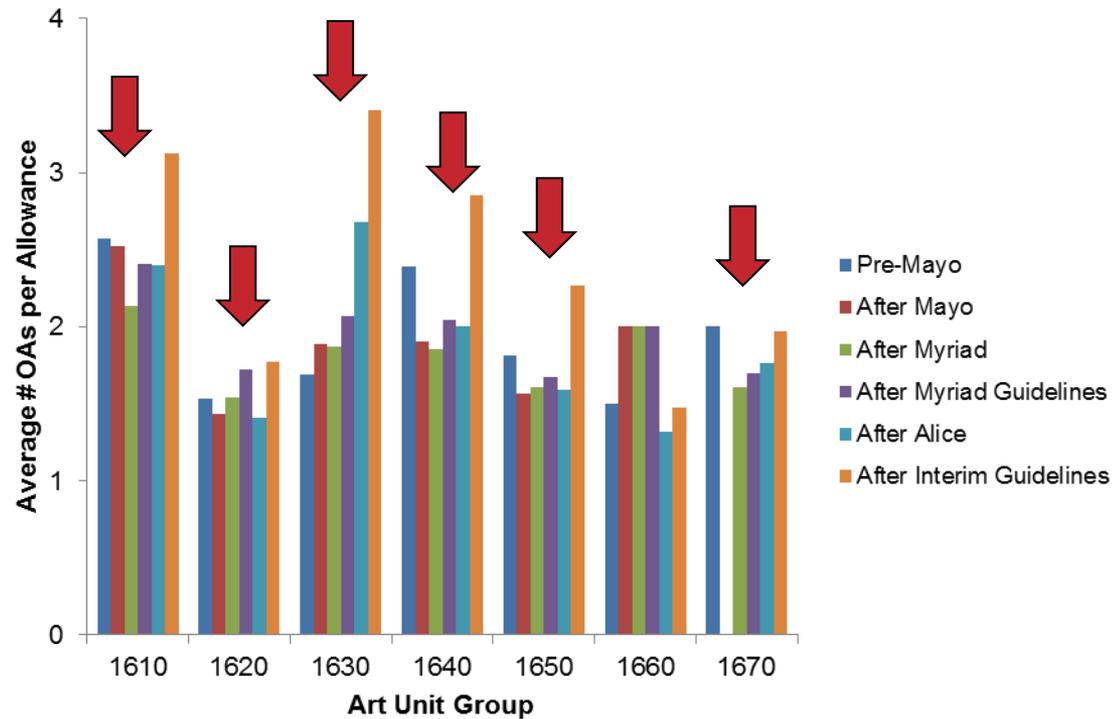
# Percentage of Allowances across Technology Centers



# Percentages of Allowances across 1600 Art Unit groups



# Number of Office Actions prior to Allowance



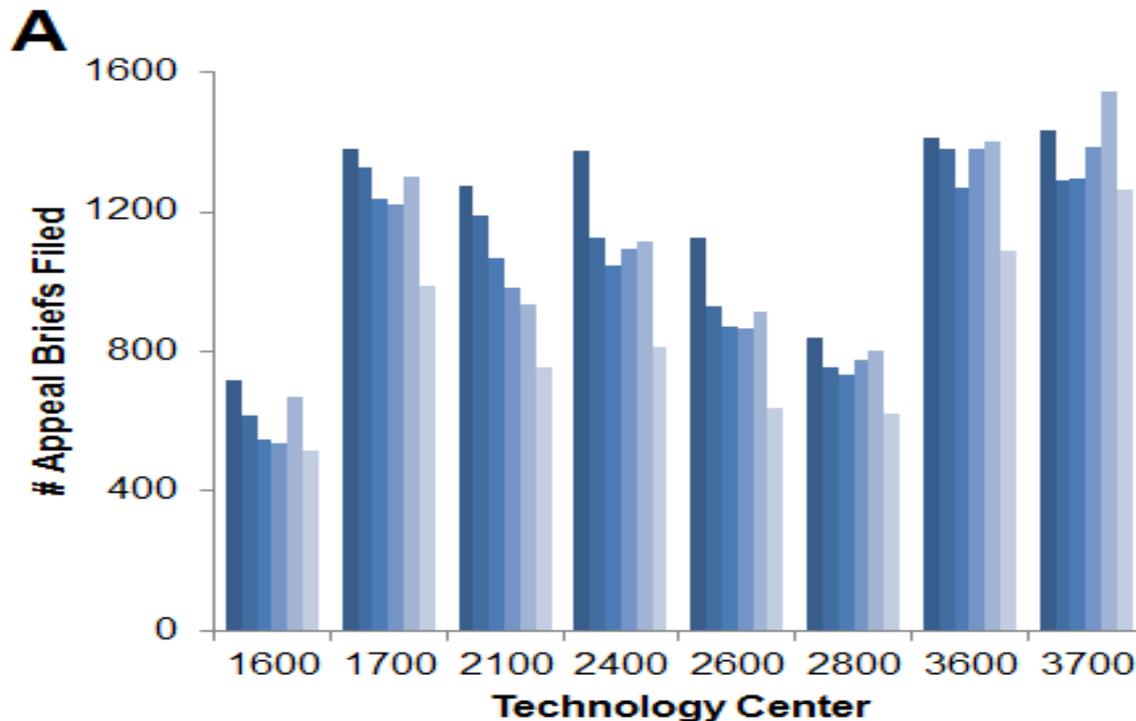
# Data related to appeals

# Appeal Data Methodology

- PTAB *ex parte* appeal database query: January 2012 – July 2015 in TC1600
- Examine all appeals for issues related to rejection of claims based on subject matter eligibility
- LexisNexis PatentAdvisor<sup>®</sup> custom query: total appeal briefs filed in TC1600 and other Technology Centers since January 2012

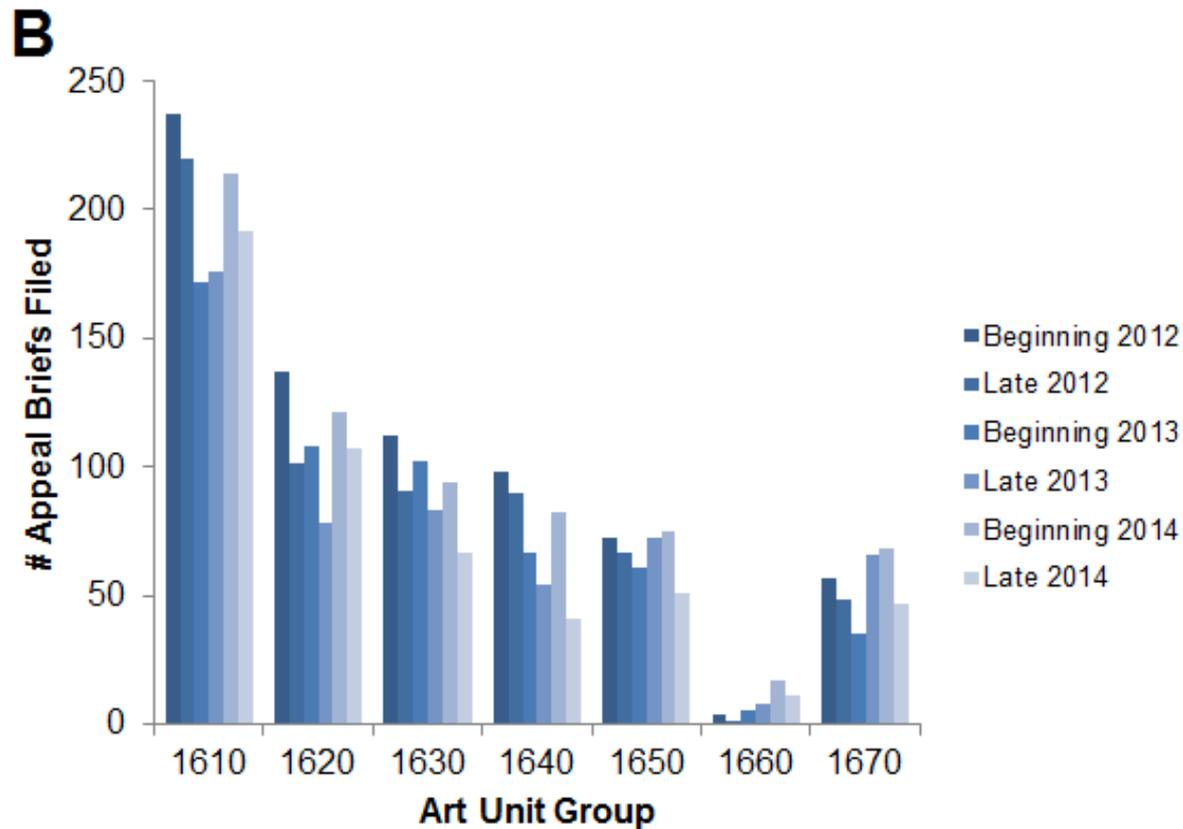
# Appeal Data

- TC1600 - Subject matter eligibility raised only once in context of interference proceeding
- TC1600 – Lower appeal rate overall compared to other Technology Centers



# Appeal Data

- TC1600 – Appeals across art-units show decrease in number of briefs filed from 2012 to 2014



# Conclusions

# Conclusions

- The 1600 Technology Center is still allowing claims
- Prosecution is more challenging and more costly
  - More 101 rejections
  - More office actions before allowance
- Some variability across art units (e.g., 1630's are particularly challenging)
- Number of appeals has decreased – uncertainty in the law?
- More data needed
  - After new guidelines and new cases
  - Effect of appeals of 101 rejections
  - Prevalence of 103 rejections (associated with 101)



# Questions/Comments

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ATLANTA  
AUGUSTA  
CHARLOTTE  
DENVER  
LOS ANGELES  
NEW YORK  
RALEIGH  
SAN DIEGO  
SAN FRANCISCO  
SEATTLE  
SHANGHAI  
SILICON VALLEY  
STOCKHOLM  
TOKYO  
WALNUT CREEK  
WASHINGTON D.C.  
WINSTON-SALEM