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Trends in Patent Prosecution

Don’t Get Left Behind

November 30, 2021

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Today's Discussion

- Trends in 101 and 112 rejections in the life sciences and high-tech sectors
- Real life examples of claim amendments that led to allowance
- Claim and drafting strategies for streamlining prosecution

Background: Measuring examiner behavior

PatentAdvisor ETA™ (Examiner time allocation) = Total office actions: total allowances issued + X factors


ETA 0 - 2.5


ETA 2.6-6


ETA 6+

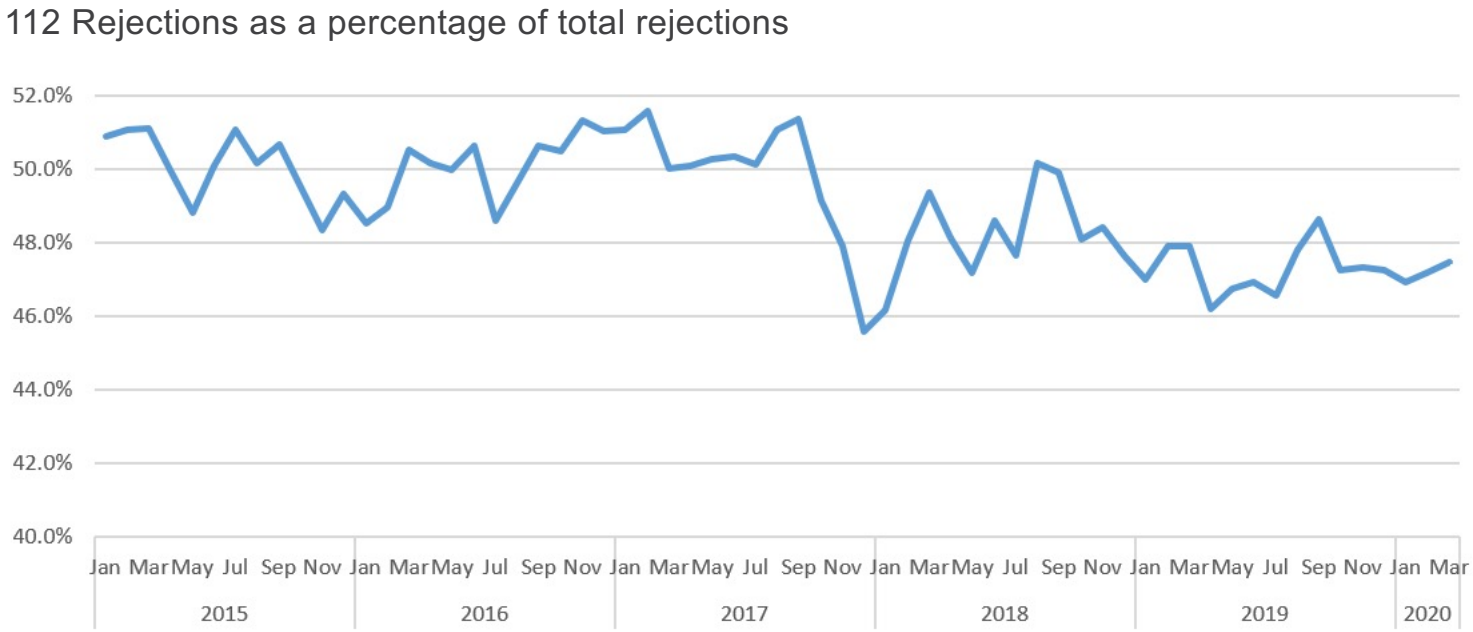
ETA is more accurate and a better predictor of examiner's behavior than Examiner Allowance Rate because it:


Includes all pending applications

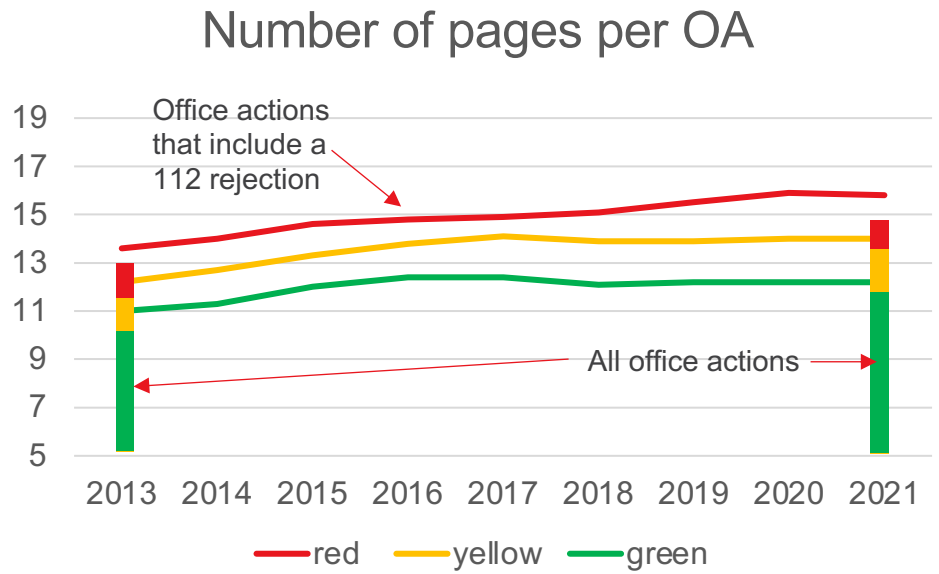

Factors in how long the examiner has been at the Patent Office


Is driven by the examiner's behaviors, not by the filer's actions

112 Rejections Over Time in 1600: Biology and Organic Chemistry



112 Rejection Complexity in 1600: Biology and Organic Chemistry



Average increase: 1.9 pages

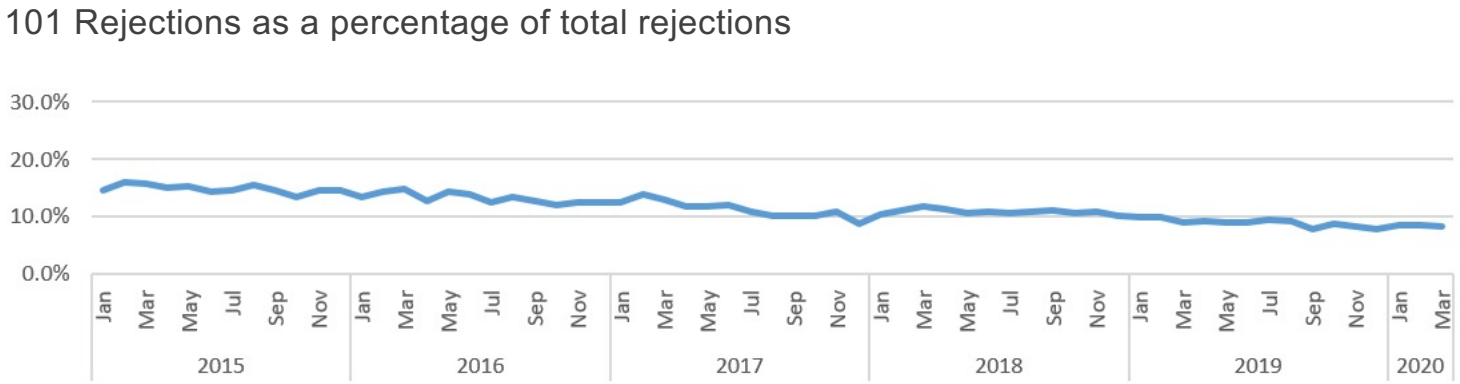
Red examiner increase: 2.2 pages

Yellow examiner increase: 1.8 pages

Green examiner increase: 1.2 pages

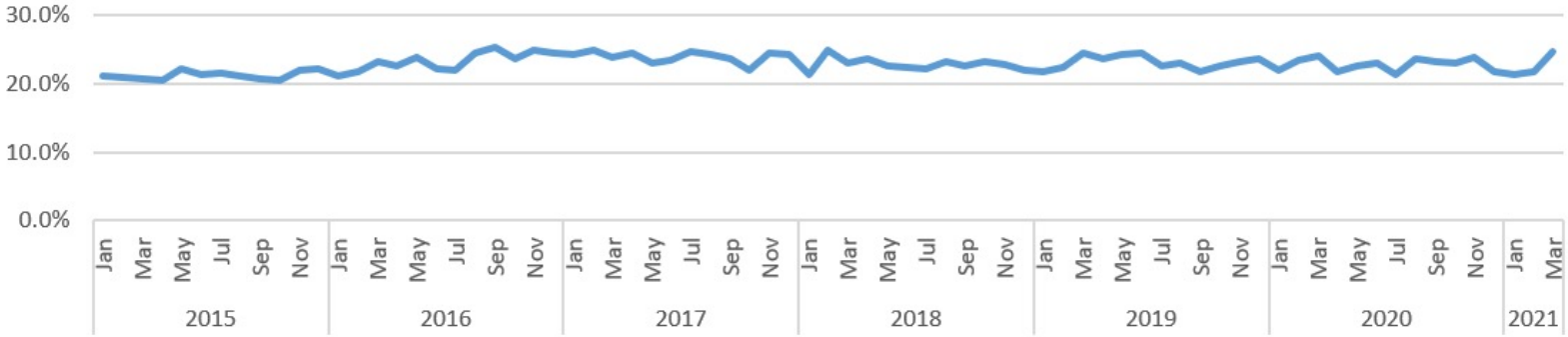
* Year indicates the year in which the application was disposed (allowed or abandoned). Office Actions for any applications filed in the past 18 months are not accounted for.

101 Rejections Over Time in 1600: Biology and Organic Chemistry

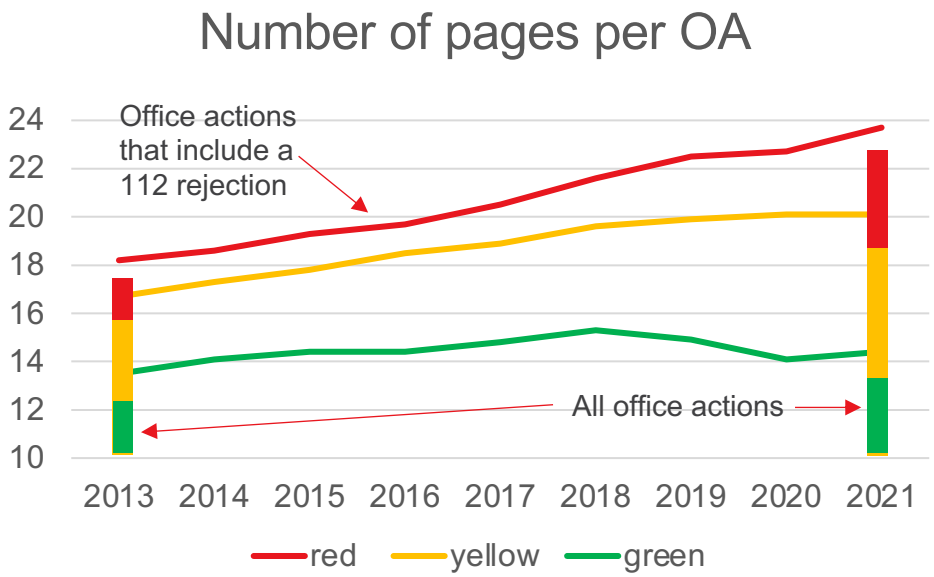


112 Rejections Over Time in 2100: Computer Architecture and Software

112 Rejections as a percentage of total rejections



112 Rejection Complexity in 2100: Computer Architecture and Software



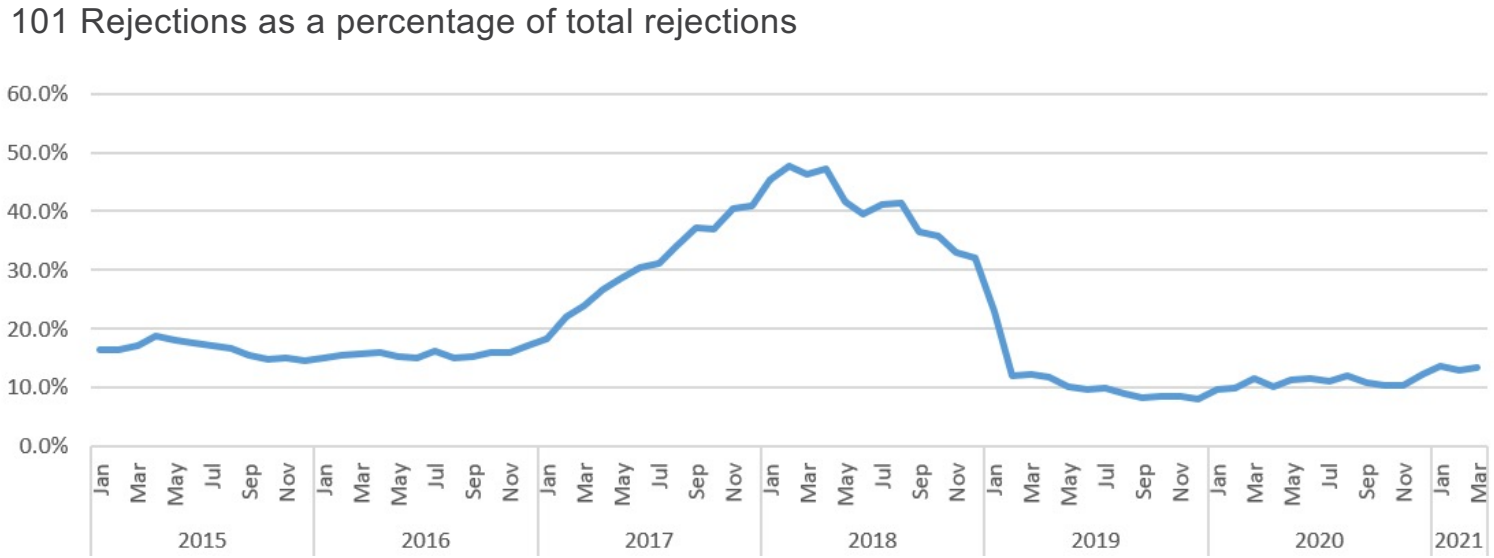
Average increase: 4.2 pages

Red examiner increase: 5.5 pages

Yellow examiner increase: 3.4 pages

Green examiner increase: 0.9 pages

101 Rejections over time in 2100: Computer Architecture and Software



Thank you!

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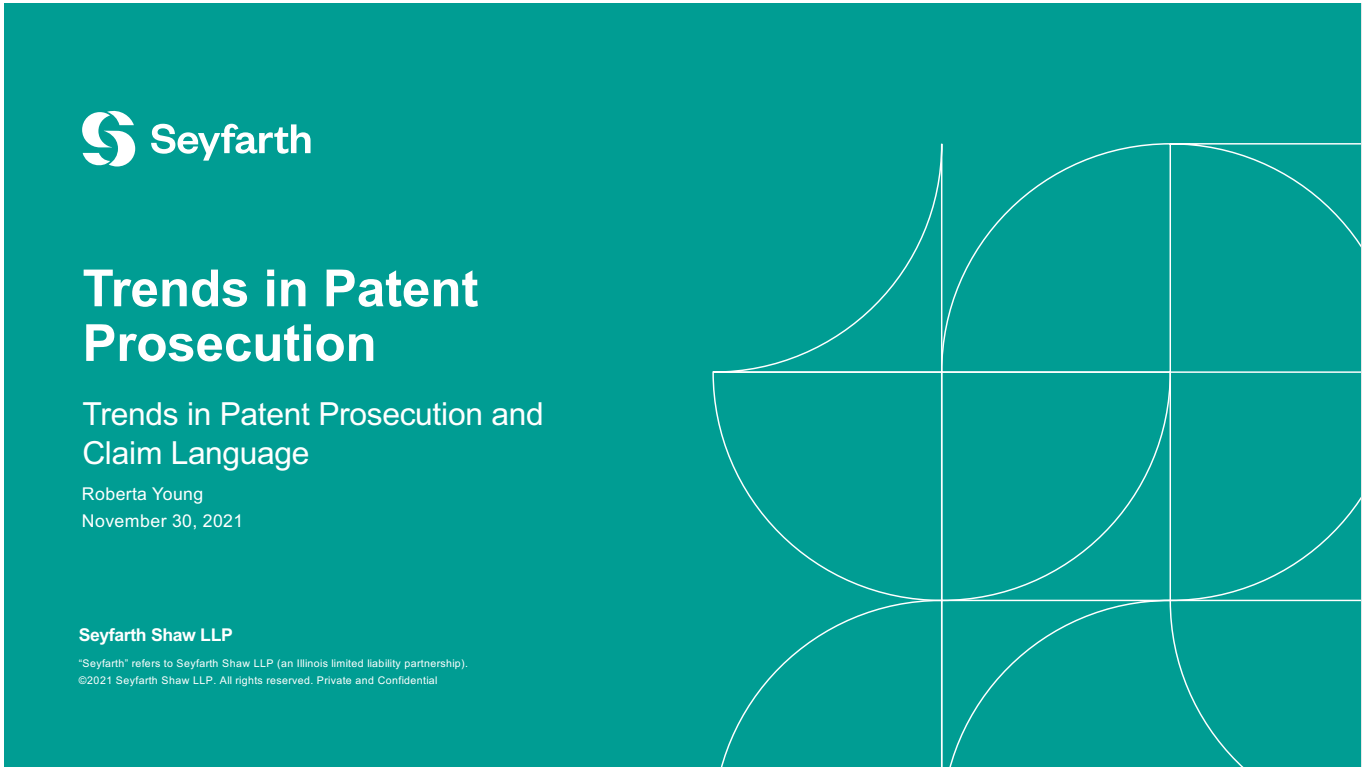
Mayo v. Prometheus (method of optimizing therapeutic efficacy) *ineligible*	**Vanda v. Westward** (method of treatment) *eligible*	**INO v. Praxair** (method of treatment) *ineligible*	**Ariosa v. Illumina** (method of preparation) *eligible*
1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the **level of 6-thioguanine less than about 230 pmol per 8×108 red blood cells indicates a need to increase the amount of said drug** subsequently administered to said subject and wherein the **level of 6-thioguanine greater than about 400 pmol per 8×108 red blood cells indicates a need to decrease the amount of said drug** subsequently administered to said subject.	9. A method of treating a patient who is suffering from a schizoaffective disorder, depression, Tourette's syndrome, a psychotic disorder or a delusional disorder, the method comprising: determining if 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 whether the patient has a **CYP2D6 poor metabolizer genotype**, and if the patient is a CYP2D6 poor metabolizer, then **internally administering iloperidone to the patient in an amount of up to 12 mg/day**, and if the patient is not a CYP2D6 poor metabolizer, then **internally administering iloperidone to the patient in an amount of greater than 12 mg/day, up to 24 mg/day**.	1. A method of treating patients who are candidates for inhaled nitric oxide treatment, which method reduces the risk that **inhalation of nitric oxide gas will induce an increase in pulmonary capillary wedge pressure (PCWP) leading to pulmonary edema in neonatal patients with hypoxic respiratory failure**, the method comprising: (a) identifying a plurality of term or near-term neonatal patients who have hypoxic respiratory failure and are candidates for 20 ppm inhaled nitric oxide treatment; (b) determining that a first patient of the plurality does not have left ventricular dysfunction; (c) determining that a second patient of the plurality has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide; (d) **administering 20 ppm inhaled nitric oxide** treatment to the first patient; and (e) **excluding the second patient from treatment with inhaled nitric oxide**, based on the determination that the second patient has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide.	1. A method for preparing a deoxyribonucleic acid (DNA) fraction from a pregnant human female useful for analyzing a genetic locus involved in a fetal chromosomal aberration, comprising: (a) extracting DNA from a substantially cell-free sample of blood plasma or blood serum of a pregnant human female to obtain extracellular circulatory fetal and maternal DNA fragments; (b) producing a fraction of the DNA extracted in (a) by: (i) size discrimination of extracellular circulatory DNA fragments, and (ii) selectively removing the DNA fragments **greater than approximately 500 base pairs**, wherein the DNA fraction after (b) comprises a plurality of genetic loci of the extracellular circulatory fetal and maternal DNA; and (c) **analyzing a genetic locus in the fraction of DNA produced in (b)**.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Trends in Patent Prosecution
Trends in Patent Prosecution and Claim Language
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November 30, 2021
Seyfarth Shaw LLP
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35 U.S.C. 101 & 35 U.S.C. 112

01 Increase in 35 U.S.C. 101 rejections of greater complexity

02 Example application – Continuation Application

03 Amendments made to receive allowance

04 Increase in 35 U.S.C. 112 rejections (a), (b)

05 Claims as filed receiving 35 U.S.C. 112 rejection

06 Amendments made to receive allowance

Increase in 35 U.S.C. 101 rejections of greater complexity

- USPTO flowchart has increased complexity.
- Examiner must establish the broadest reasonable interpretation of the claims as a whole.
- Examiner must determine if claim is directed to a statutory category.
- Review carefully to determine that all steps of analysis have been performed and completely discussed by the examiner.
- Look for conclusory statements, incomplete analysis
- 101 rejections are increasing in length, this 101 rejection was over 8 pages.

Example Application – Continuation Application

- Continuation application filed September 2017.
- Parent application filed January 2013.
- Specification does not reflect current application drafting practice. specification provides a fairly generic discussion of an electronic record system.
- Independent claims were directed to an electronic record information system comprising: a secure memory and a processor. The processor is programmed to access multiple web services for secure data records.
- The secure records relate to individuals represented in the data accessed from the web services.
- Based on the records, a target individual is grouped into population cohorts.
- A clinical condition is attributed to the target individual based on the secure data records.

Amendments made to receive allowance

- Clarify and simplify claim language.
- Emphasize how the processor matches records of individuals across the multiple web services.
- Focus on the technical details of the improvements to the processor and the user interface.
- A fairly extensive amendment was made in response to the final office action, focusing on details of the user interface.
- The amendment led to an examiner requested interview that resulted in allowance with a far less extensive amendment than previously presented.

Increase in 35 U.S.C. 112 (a) & (b)

- 112 rejections more common and more complex.
- Both (a) & (b) rejections issued in most applications.
- For 112 (a) examiners allege that the specification is non-enabling for specific technical features.
- The features are alleged to be missing and required.
- For 112 (b) the examiner then uses the same argument to allege that the application does not point out and distinctly claim the invention.
- When this allegation is made, the examiner has alleged that an element is missing from the specification and claims.
- Examiners have also alleged that claims are indistinct for recitations that do not specifically enumerate functionality with respect to other elements.

Example Application Claim

- Independent claims directed to a method of setting an operating voltage of a shared power rail.
- The method includes identifying voltage specifications for each core in a multi-core device, receiving reports of core operating states from each core in the device, determining an operating voltage for the shared power rail, and programming the voltage regulator.

Amendments made to receive allowance

- Clarifying amendments were made that detailed where a voltage specification was received and from what element.
- Further clarifying amendments were made to indicate how the selection of the operating voltage was made.
- The amendments also included how the selected operating voltage was programmed into the voltage regulator.

There is no off position on the genius switch.

David Letterman

thank you

contact information

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