Routine Optimization: A Performance Review

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Routine Optimization is one of only a few legal doctrines which allow for the formation of a prima facie case of obviousness while admitting that the combined teachings of the cited prior art fail to teach every feature of a claimed invention.[1] A rejection which relies upon routine optimization is therefore fundamentally different from a standard rejection obviousness rejection under 35 USC § 103 because the Examiner is admitting that the cited prior art fails to teach every feature of the claims, i.e., the claimed range being optimized to.

Therefore, if the underlying basis for reliance on the routine optimization doctrine is improper or unjustified, the rejection as a whole must fail.

The United States Patent and Trademark Office in its Manual of Patent Examining Procedure traces the caselaw regarding routine optimization doctrine back to 1955 and the *In re Aller* decision holding "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."[2] However, the doctrine itself and the principal which it seeks to capture traces it roots back much further. *In re Aller* itself can be traced back to the 1875 Supreme Court ruling of *Smith v. Nichols*[3] which defined the principal which would become routine optimization as, "It is the invention of what is new, and not the arrival at comparative superiority or greater excellence in that which was already known, which the law protects as exclusive property and which it secures by patent." That is, invention requires something more that the mere distillation of prior art into its most efficient form. The Court believed then and has maintained to the present day that mere optimization is not invention.

While the founding principles above for the routine optimization doctrine largely remain unchallenged, the actual method for deciding whether the presented claims are inventive or merely a more efficient form of the prior art, has evolved in the modern day. The modern analysis for routine optimization doctrine has added certain checkpoints in the analysis which have helped to add certainty and increased objectivity to the ultimate determination of

[1] *See also,* for example, the doctrines of Inherency and Design Choice.
[2] *In re* Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also MPEP § 2144.05(II).
[3] *Smith v. Nichols*, 88 U.S. 112, 22 L. Ed. 566, 21 Wall. 112 (1875).

obviousness when using routine optimization. MPEP § 2144.05 has largely codified the modern caselaw on this topic and arrived at the following steps for using the routine optimization doctrine:

1. Determine whether there is at least overlap in the teachings of the prior art and those claimed.[4] That is, if the prior art teachings do not at least overlap with claimed subject matter, there is nothing which can be optimized to result in the claims.
2. However, mere overlap alone is insufficient for a finding of routine optimization. The prior art must also teach a result effective variable. A result effective variable is a variable which achieves a recognized result. See *In re Antonie*.[5] That is, in order to optimize, one skilled in the art would need something in the prior art to manipulate to move toward in the identified optimal result (the result-effective variable).[6] Without at least satisfying this condition, one skilled in the art would not arrive at the claims of the current application through routine optimization. See *In re Applied Materials*.[7]
3. Even once a result effective variable has been identified "some rational underpinning explaining why a person of ordinary skill in the art would have arrived at the claimed invention." See *In re Stepan Co*.[8] That is, the optimization taught by the cited prior art must lead to the subject matter of the claims. If instead the art teaches optimization of a result effective variable in a manner which results in embodiments which fall outside the claimed subject matter, a rejection reliant upon routine optimization is improper.[9]

A rejection based upon routine optimization is proper if the rejection of record satisfies all three requirements discussed above. The procedural function of the Examiner making a prima facie case based on the routine optimization is to shift the burden to Applicants to prove that the claims are not obtainable through routine optimization or that the claimed range is critical to providing some desired result.

Satisfying this rebuttal burden may be achieved by applicants by undermining the underlying veracity of the above three requirements or by demonstrating the criticality of the claimed range within the teachings of the cited prior art.[10] This criticality requirement is essentially the same as the unexpected results standard.

[4] *In re* Peterson, 315 F.3d at 1330 (Fed. Cir 2003).

[5] *In re* Antonie, 559 F.2d 618, (CCPA 1977); See also MPEP § 2144.05(II)(B).

[6] See the precedential PTAB decision *In re* Whalen, Appeal No. 2007-004423 which applies *In re* Antonie.

[7] *In re* Applied Materials, 692 F.3d 1289 (Fed. Cir. 2012).

[8] *In re* Stepan Co., 868 F.3d 1342, 1346 (Fed. Cir. 2017).

[9] *Genetics Institute, LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1306 (Fed. Cir. 2011); *see also, Ex parte Oldorff*, Appeal 2019-6435 citing *In re* Stepan Co.

[10] "One way in which the patentee may rebut the presumption of obviousness is by showing 'that there is something special or critical about the claimed range.'" One way in which the patentee may rebut the presumption of obviousness is by showing "that there is something special or critical about the claimed range." *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1341, (Fed. Cir. 2020) citing *E. I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996 (Fed. Cir. 2018).

For example, consider a claim directed to 20%-25% of component X where the prior art teaches 5%-50% of component X. Applicants could present argument and/or evidence either that the taught result effective variable of the prior art did not optimize to result in embodiments with 20%-25% of component X or applicants could show that embodiments which possess 20%-25% of component X have some property or feature that embodiments having 5%-19% and 26% to 50% do not.

Measuring How Applicants and Examiners Are Handling the Routine Optimization Doctrine

In order to properly evaluate how the Examiners and Applicants are handling the routine optimization doctrine there is a need for a method for objectively measuring this single argument type within the broader universe of obviousness rejections. The method used herein, relies on decisions by the Patent Trial and Appeal Board (PTAB) as a proxy for determining whether an Examiner was correct or not when rejecting a particular claim under the routine optimization doctrine. The method compares Examiner affirmance and reversal rates in rejections which relied on the routine optimization doctrine to general affirmance and reversal rates of the same type, i.e., generic obviousness rejection.

The data below was acquired by reviewing every PTAB decision from September 2017 to September 2020 which included the phrase "routine optimization." Each decision which used this phrase was reviewed to determine whether the routine optimization doctrine was actually at issue. In the cases where the routine optimization doctrine determined to be at issue, the decision with regard to the obviousness rejection was recorded.

The data shown below obtained by the method above is further separated by Technology Center. This data is then compared to the general rates of reversal/affirmance of obviousness rejections.[11]

Routine Optimization Rejection Data

Tech Center	103 Affirmed	103 Reversed
1600	66%	34%
1700	62%	38%
2100	NA	NA
2400	NA	NA
2600	NA	NA
2800	54%	46%
3600	50%	50%
3700	41%	59%

[11] Pool, R. (n.d.). *Should You Appeal*.100 J. Pat. and Trademark Off. Soc'y, 320 (2018).

Sample Sizes:

The doctrine of routine optimization is not equally used across all Technology Centers (TC) in the USPTO. Instead the TCs can be broken down into three tiers by the relative frequency of the doctrines use.

Tier 1 (most frequent use): 1600, 1700, and 3700
Tier 2 (occasional use): 2800 and 3600
Tier 3: (rarely, if ever, used): 2100, 2400, and 2600

Tier 1 TCs use routine optimization at rate five times higher than Tier 2 TCs. Tier 3 TCs, rarely if ever use routine optimization. In the three-year time span studied, these TCs had three or less relevant decisions which turned on routine optimization. Due to the limited sample size in these Tier 3 TCs, the data is not expressed as a percentage above.

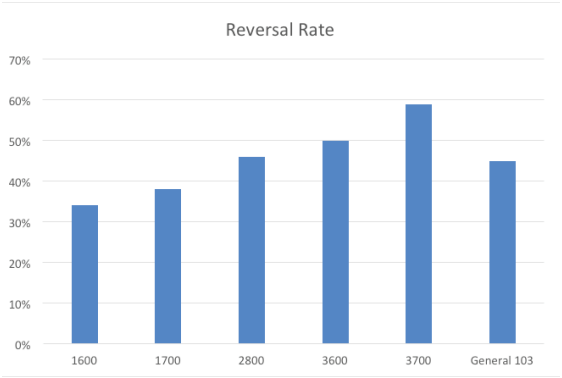
To help put the affirmance and reversal rates into context, the general rates of reversal/affirmance of obviousness rejections (35 USC 103) is

35 USC 103: Affirmed 49.7% Reversed: 40.5% Affirmed-in-Part: 9.7% [12]

To account for Affirmed-in-Part percentage and allow for a more direct comparison to the data above the above data is converted to a general rate calculated by assuming the same affirmance to reversal ratio is maintained in the Affirmed-in-Part decisions.

35 USC 102: General Affirmance Rate: 44.5% - Average Reversal Rate: 55.5%)
35 USC 103: General Affirmance Rate: 55.1% - Average Reversal Rate: 44.9%)

While the comparison to these general decision rates for rejections under 35 USC 102 and 35 USC 103 is not exactly a perfect comparison, it useful of viewing the data in a relevant context. For ease of comparison the above data is compiled in the graph below. The graph shows the reversal rates for rejections based on routine optimization. The data is organized by Technology Center and the last data group is composed of the general rates of reversals for rejections under 35 USC 103.



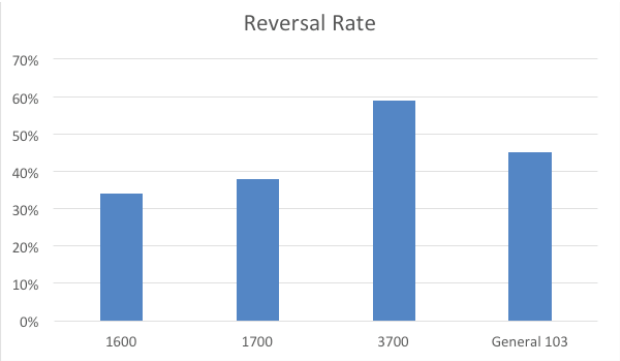
[12] Id.

Lessons from the Study

The overall average reversal rate when considering every case in the study was 44% which is essentially the same as the reversal rate of a generic 103 rejection (45%). However, there is a 25% difference in the reversal rate between the highest reversal rate TC (3700) and the lowest reversal rate TC (1600) indicating that technology area is a significant factor in predicting an applicant's chances for reversal of a rejection on appeal.

The study revealed differences between the TCs which handle the bulk of routine optimization cases and those where the issue only rises on occasion. For example, when comparing Tier 1 and Tier 2 TCs, it is notable that all Tier 1 TCs diverge more drastically from the reversal rates of a general 103 rejection than any of the Tier 2 TCs (Tier 2 TCs are within 5% of general 103 rejection reversal rate while Tier 1 TCs push 15% divergence). Of the Tier 1 TCs, 1600 and 1700 were reversed at a lower rate than a general 103 rejection while TC 3700 saw its decisions reversed more frequently when relying upon routine optimization to support its rejections. The Tier 2 TCs performance was more inline with reversal rates of a general 103 rejection, however, both were slightly more likely to be reversed. Only the rejections in TC 3700 were more likely than not to be reversed by the Board.

Tier 1 TCs:



TC 1600 relates to "Biotechnology and Organic fields," TC 1700 relates to "Chemical and Materials Engineering fields," and TC 3700 relates to "Mechanical Engineering, Manufacturing and Products."[13] This group of technology fields in Tier 1 notably leaves out essentially all arts related to computers and electronics.

It is notable that the reversal rates of TC 3700 are almost double that of TC 1600 and significantly higher than TC 1700. It therefore cannot be reasonably said that the frequency with which Examiner's handle routine optimization is solely responsible for the increased performance of TC 1600 and TC 1700 on appeal.

[13] *See* USPTO Technology Center definitions https://www.uspto.gov/patent/contact-patents/patent-technology-centers-management (last visited September 29, 2020).

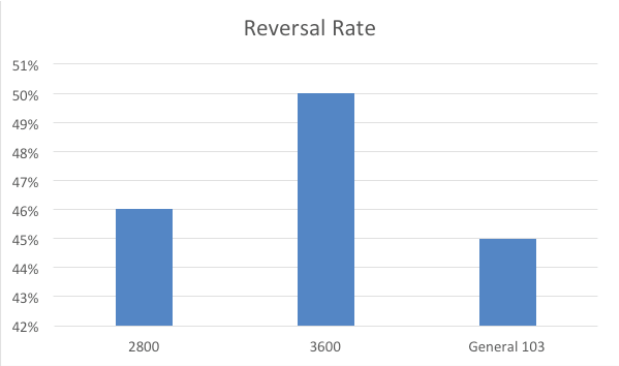
A hypothesis for the exhibited performance differences of these Technology Centers is type of subject matter being examined. The subject matter being rejected using routine optimization in TCs 1600 and 1700 are often similar in structure with similar kinds of teachings present in the prior art. These rejected claims are often drawn to compounds or compositions where the prior art teaches the claimed components just not in the specifically claimed ranges of those components in the claims. Routine optimization is used to bridge the gap between the broader ranges of the prior art and the narrower claim ranges.

In these cases, the PTAB is rarely impressed with mere performance improvement by the claims achieved by their narrower ranges (performance improvement must be significant). The PTAB often requires evidence that the narrower claim range result in a difference in kind rather than just degree, i.e., the emergence or absence of some desirable or undesirable property, respectively.

TC 3700 deals with mechanical subject matter where the claimed ranges are often not just relative component amounts, but include ranges having to do with volume, size, weight, density, or other relevant properties of those components which combine for some particular benefit.

The PTAB also was much more likely to accept arguments attacking the prima facie case in applications in TC 3700 than for applications in TCs 1600 and 1700. For example, rejections were reversed much more often in TC 3700 on the basis that the Examiner failed to properly identify a result effective variable which could be optimized to result in the claimed range. These same kinds of arguments where presented in the TC 1600 and 1700 appeals but resulted in reversal less frequently.

Tier 2 TCs:



TC 2800 relates to "Semiconductors, Electrical and Optical Systems and Components" and TC 3600 relates to "Transportation, Electronic Commerce, Construction, Agriculture, Licensing and Review."[14]

[14] *See* USPTO Technology Center definitions https://www.uspto.gov/patent/contact-patents/patent-technology-centers-management (last visited September 29, 2020).

These tier 2 tech centers each had less than 20 decisions rendered regarding routine optimization over the 3-year period reviewed in this paper. Not shown in the data above was that if one looked as any 6-month period of decisions in the 3-year period studied, one would fine the ratio of affirmed to reversed decisions held fairly constant at around 50:50. Therefore, although the sample size is relatively small, it appears that one could reasonably expect this 50:50 trend to continue into the future barring some catalytic event in the field.

The facts in the cases tend to look more like those of TC 1600 and 1700 rather than TC 3700. For example, the claims in the semiconductors field tend to look very similar to the claims in TCs 1600 and 1700 as they are often directed to different wt% of specific components. The rejected claims in other areas of TCs 2800 and 3600 are often directed to ranges of, for example, frequencies, voltages, current, etc. where the prior art teaches a broad overlapping range. Prevailing arguments on the part of applicants tended to focus the prior art failing to identify a result effective variable and the presence of some property present in the claimed range but absent from the prior art teaching.

Despite these similarities to the cases of TCs 1600 and 1700, the reversal rates in TCs 2800 and 3600 are on average, about 29% higher. The exact reason for this difference is not known. It could be that because Examiners in TCs 2800 and 3600 have less experience with routine optimization rejections which result in the rejections they draft simply not being as strong as their more experienced colleagues in TCs 1600 and 1700. It could also be that the technology differences (electrical vs chemical) explain some if not most of the differences in results of the appeals. Lastly, the PTAB itself is separated somewhat by technology specialties. Therefore, the different reversal rates might be partially explained by the relative view points of the Judges themselves on routine optimization rejections.

Tier 3 TCs:

TC 2100 relates to "Computer Architecture Software and Information Security," TC 2400 relates to "Computer Networks, Multiplex, Cable and Cryptography/ Security," and TC 2600 relates to Communications.[15] In the three-year time span studied, TC 2100 had only one relevant decision and resulted in affirmance of the rejection. TC 2600 had three relevant decision and in all three decisions the Board reversed the Examiner's rejection based on routine optimization. TC 2400 had no relevant decisions. It is difficult to draw any general trends from such a limited data set. It seems likely that the structure of the claims in these art areas simply do not lend themselves to rejections based on routine optimization and likely rarely claim specific ranges.

In re Stepan Co.

By far, the most frequently cited case in appeal decisions which resulted in a reversal of a rejection based on routine optimization was *In re Stepan Co*.[16] This

[15] *Id*.
[16] *In re* Stepan Co., 868 F.3d 1342, 1346 (Fed. Cir. 2017).

2017 decision from the Federal Circuit reversed a PTAB decision affirming a rejection based on routine optimization. In its decision, the Federal Circuit finds multiple flaws with the PTAB's affirmance of the rejection to the claims including that the PTAB failed to make sufficient factual findings to justify its finding of obviousness based on routine optimization, that there was insufficient evidence to support that one skilled in the art would have a reasonable expectation of success in arriving at the claims, and that the PTAB engaged in improper burden shifting to the applicant to show criticality without first providing sufficient evidence to justify a prima facie case based on routine optimization.[17]

In the PTAB decision which was appeal to the Federal Circuit the Board held:

> it is routine optimization to select and adjust the surfactants to this range since Pallas teaches the surfactant component comprises any combination of surfactants. Pallas may not teach a cloud point above 70 degrees Celsius, but Pallas does teach the ideal cloud point should be above 60 degrees or more [0029]. Therefore, optimizing the formulation so as to achieve a cloud point higher than 60 degrees Celsius is suggested by the teachings of Pallas et al.[18]

In direct response to this finding the Federal Circuit held, "Reciting Pallas' teachings that 'any combination' of surfactants may be used and that a cloud point above 60ºC is desired fails to illuminate why a skilled artisan would have selected the claimed combination of surfactants and reasonably expected a cloud point above at least 70ºC."[19] The Court reminded that routine optimization is merely a tool for answering the ultimate question of obviousness. Questions like, would one skilled in the art ultimately have a reason to arrive at the claimed invention from the teachings of the prior art could not be left out of a proper analysis even when routine optimization was used in constructing the prima face case.

The application which was the subject of the *In re Stepan Co*. decision was examined in TC 1600. It is somewhat ironic that the seminal modern Federal Circuit case for reversing routine optimization rejections came from Technology Center with the best record for affirmances at the PTAB.

The holding of *In re Stepan Co*. reminds that regardless of what legal doctrines are used to construct a prima facie case of obviousness, for the rejection to be proper, ultimately it must clearly articulate how and why one skilled in the art would arrive at the claims under examination from the teachings of the prior art. The teaching of an overlapping range and a result effective variable are more that mere boxes to be checked before a rejection can be issued. Instead, these are intended to be guild posts for determining the ultimate question of obviousness which is would one skilled in the art arrive at the claimed invention from the teachings of the cited prior art.

[17] *Id*.
[18] *Ex parte* Malec, Appeal 2013-5196, 2017 BL 470864.
[19] *In re* Stepan Co., 868 F.3d 1342, 1347, (Fed. Cir. 2017).

Result Effective Variable

One issue not discussed in *In re Stepan Co*. is that routine optimization requires an art recognized Result-Effective Variable. A result-effective variable is a variable which "achieves a recognized result."[20] Such variable must be identified, "before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.[21] In *In re Antonie*, the court held that a variable is not a result effective variable if the prior art provides no teaching of the claimed relationship and also 'no evidence of this relationship in the prior art".[22] Looking back on its decision in *In re Antonie,* the Court in 2018 held:

> The idea behind the "result-effective variable" analysis is straightforward. Our predecessor court reasoned that a person of ordinary skill would not always be motivated to optimize a parameter "if there is no evidence in the record that the prior art recognized that [that] particular parameter affected the result.[23]

This requirement is based in logic. In order to optimize, one skilled in the art would need something in the prior art to manipulate to move toward in the identified optimal state (the result-effective variable). Without at least satisfying this condition, one skilled in the art could not arrive at the claims of the application under examination through routine optimization.

However, in cases where the prior art does teach a relationship between a variable and an affected property, the prior art is not required to "provide the exact method of optimization for the variable to be result-effective."[24] That is, the prior art need not recognize the same reason or method for optimization discovered by the applicant, the art need only recognize the variable has some relationship with the relevant property.

The question of whether a taught variable has some relationship with the relevant property can be more complex than it first appears. Clearly, the failure to teach any relationship between variable and property is not enough, but a "comprehensive explication of the known relationships between the variables and the affected properties," is not required to justify a prima facie case.[25] However, there appears room for argument where the prior art and claims teach completely different relationships between relevant variables and property. There is also a grey area where the taught/claimed variable and property are the same, but the prior art actively teaches away claimed range. To resolve these arguments the Court in *In re Stepan Co*. reminded that at the end of any obviousness analysis the ultimate question which must be decided

[20] *In re* Antonie, 559 F.2d 618, (CCPA 1977).
[21] *Id.*
[22] *Id.*
[23] *E. I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018).
[24] *In re* Applied Materials, Inc., 692 F.3d 1289, 1297 (Fed. Cir. 2012).
[25] *Id.*

is whether or not the teachings of the cite prior art would provide a reason for one skilled in the art to arrive at the claimed invention with a reasonable expectation of success. The doctrine of routine optimization is merely a tool to achieve this goal.

Conclusion

When considering any of the specific prongs of the routine optimization analysis it is important to keep in mind the purpose for its existence as articulated by the Supreme Court almost 150 years ago which is to distinguish "what is new, and not the arrival at comparative superiority or greater excellence in that which was already known."[26]

The appropriateness of relying upon routine optimization to formulate a rejection under 35 USC § 103 appears to be at least somewhat affected by the technology field in which the invention resides. Regardless of technology field, however, where an overlapping prior art range exists it must be determined whether or not the prior art includes the teaching of a result effective variable and whether the overlapping range and result effective variable ultimately give one skilled in the are a reason to optimize to the claimed range and a reasonable expectation of success when doing so.

[26] *Smith v. Nichols*, 88 U.S. 112, 22 L. Ed. 566, 21 Wall. 112 (1875).