



2021 WINTER NEWSLETTER

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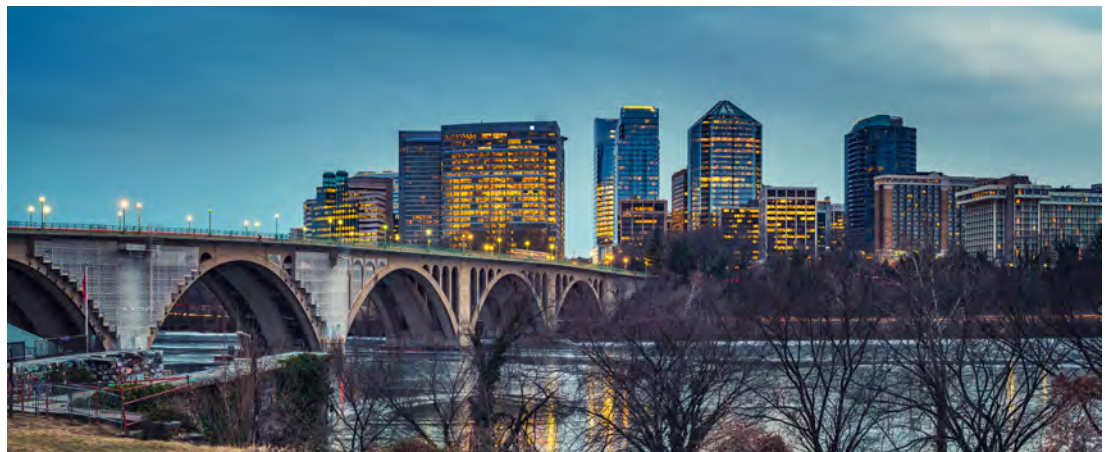
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U.S. SUPREME COURT

United States v. Arthrex Inc.
Constitutionality of PTAB Judge Appointments

By: Gene M. Garner II, Partner
An Nguyen, Law Clerk

A recent case between two medical device companies raised the question of the constitutionality of the method in which Patent Trial and Appeal Board (PTAB) judges are appointed. PTAB judges are administrative patent judges who examine patents whose validity is questioned and hear appeals from patentees whose patent applications have been rejected. More specifically, PTAB judges hear appeals from adverse examiner decisions in patent applications and reexamination proceedings, conduct America Invents Act (AIA) trial proceedings, and hear interference proceedings. The PTAB is an administrative court run by the USPTO and was created by Congress as part of the AIA.

The case at issue was appealed to the U.S. Supreme Court after the lower court held that the method of appointment of PTAB judges, by the Secretary of Commerce, was unconstitutional as a violation of the Appointments Clause of the United States Constitution. Found in Article II, Section 2, Clause 2 of the United States Constitution, the Appointments Clause states:

“... and [the President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.”

The issue in question is whether PTAB judges are considered “principal officers” that require nomination by the President and confirmation by the U.S. Senate. An alternative interpretation is that PTAB judges are “inferior officers,” who have less authority and can be appointed and supervised by a department head. Currently, PTAB judges are appointed by the Secretary of Commerce and have certain job protections from unrestricted removal from their posts. While the Federal Circuit agreed that the appointment of PTAB judges does violate the Constitution, the Federal Circuit stated that the method of appointment could be cured by removing these job protections in order to render the judges inferior officers. The case was argued in early March and the ruling is expected by the end of June.

U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Amgen v. Sanofi and Regeneron
Enablement and the In re Wands Factor

By: Raph Kim, Associate

On February 11, 2021, the Court of Appeals for the Federal Circuit (“Federal Circuit”) affirmed a district court’s judgment as a matter of law (“JMOL”) that Amgen’s asserted claims to partial structures of antibodies were invalid for lack of enablement, holding that undue experimentation would be required to practice the invention claimed.

This case provides the Federal Circuit’s further guidance on the determination of enablement based on In re Wands factors, while such a determination based on the In re Wands factors still largely depends on factual analysis.

Amgen Inc. (hereinafter, “Amgen”) appealed from a decision of the District Court for the District of Delaware granting JMOL of lack of enablement of claims 19 and 29 of U.S. Patent 8,829,165 (the “‘165 patent”) and claim 7 of U.S. Patent 8,859,741 (the “‘741 patent”). These claims in the ‘165 patent and the ‘741 patent are directed to antibodies that bind to one or more of fifteen amino acid residues of a convertase enzyme, to interfere with the convertase enzyme (PKSK9)’s ability to remove receptors binding to low-density lipoprotein (“LDL”) receptors. These LDL receptors perform a function of removing LDL cholesterol from the bloodstream by binding to the LDL cholesterol. Therefore, blocking the convertase enzymes with the antibodies would have an effect on lowering LDL cholesterol. The court found that the claimed antibodies were defined by their function of binding affinity to specific amino acid residues on the PCSK9 enzyme and blocking the PCSK9/LDL receptor interaction. The specification was said to disclose amino acid sequences for twenty-six antibodies species of the claims, including the antibody marketed by Amgen as Repatha®.

This case is the most recent case from the long procedural history since October 17, 2014, when Amgen filed suit against Sanofi, Aventisub LLC (collectively, “Sanofi”) alleging infringement of the ‘165 patent and the ‘741 patent.

The enablement requirement set forth in 35 U.S.C. §112 requires patent specifications to enable any person skilled in the art to make and use the patented invention. To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not have been able to practice the claimed invention without undue experimentation. In determining the enablement, the Federal Circuit applies In re Wands factors for guidance. In re Wands factors provide guidance on the factual considerations that a court may consider when determining whether the amount of that experimentation is either undue for enablement or sufficiently routine such that an ordinarily skilled artisan would reasonably be expected to carry it out. The elements of In re Wands factors are:

(1) the quantity of experimentation necessary,

U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Amgen v. Sanofi and Regeneron

Enablement and the In re Wands Factor (*cont.*)

- (2) *the amount of direction or guidance presented,*
- (3) *the presence or absence of working examples,*
- (4) *the nature of the invention,*
- (5) *the state of the prior art,*
- (6) *the relative skill of those in the art,*
- (7) *the predictability or unpredictability of the art, and*
- (8) *the breadth of the claims.*

Here, in determining *the breadth of the claims*, the Federal Circuit found that the scope of the claims was indisputably broad. Instead of looking only at the number of possible embodiments falling within the claims, the court was “concerned with their functional breadth” and held that the claims are “far broader in *functional* diversity than disclosed examples” in the Specification.

In determining *the predictability or unpredictability of the art, the nature of the invention, and the amount of direction or guidance presented*, the Federal Circuit held that the invention is “in an unpredictable field of science with respect to satisfying the full scope of the functional limitations”. Based on the evidence, the Federal Circuit held that only “a small subset of examples of antibodies can predictably be generated.” The Federal Circuit found that “[h]ere, even assuming that the patent’s ‘roadmap’ provided guidance for making antibodies with binding properties similar to those of the working examples, no reasonable factfinder could conclude that there was adequate guidance beyond the narrow scope of the working examples that the patent’s ‘roadmap’ produced”, and that, after considering the disclosed roadmap for producing the claimed antibodies in view of the unpredictability of the art would lead a reasonable fact finder to conclude that the patent does not provide significant guidance or direction to a person of ordinary skill in the art.

In determining *the quantity of experimentation necessary*, the Federal Circuit also determined that obtaining the claimed embodiments outside the scope of the disclosed examples and guidance would take undue experimentation. A person having ordinary skill in the art could only do so through an involved trial and error process by making changes to the exemplary antibodies and screening for functionality or by discovering them via a randomization-and-screening roadmap.

In view of the In Re Wand factors considered by the Federal Circuit, therefore, the court held that this process on the facts would be undue experimentation and the enablement requirement under § 112 is unmet, invalidating the claims at issue.

Since the In re Wands decision, the Federal Circuit began to discuss the *full breadth* of the claim in the context of enablement. This Federal Circuit’s decision will likely have an effect on claiming purely for antibodies’ binding affinity (functionality), as it may be practically difficult to provide a sufficient number of examples of antibodies to support enablement for the full breadth of a claim. The case is also a good reminder to avoid unreasonably broad claiming and to draft the Specification to include a broad base of examples, such that the disclosure is “commensurate with the scope of the claims” being claimed.

U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

**“AT LEAST ONE ...”
The Trend to Clarify Ambiguities**

By: Mehdi Sheikerz, Partner

Claim definiteness is increasingly playing a more critical role in claim construction, considering the scrutiny afforded petitioners in inter-partes examination proceedings (IPRs) challenging validity of patents before the USPTO. Even though indefiniteness is not a basis to institute an IPR, claim indefiniteness can cause claim construction confusion.

The trend to clarify ambiguities and therefore avoid indefiniteness in claim language may have started before availability of IPRs as indicated by the *Superguide Corp v. DirectTV Enterprises, Inc.*, 358 F.3d 870 (Fed. Cir. 2004) decision where the short claim expression “at least one” modifying a list of items caused considerable ambiguity in interpreting the claims of the patent.

In the *Superguide* decision, the court decided that “at least one” before a list of items modifies each item in the list, so that the claim requires each of the items in the list to be present for literal infringement. The court based its decision on the fact that the specification did not provide alternative examples where other combinations of the listed items may be contemplated.

Subsequent Federal Circuit decisions seem to have also adopted the *Superguide* reasoning to some extent. In *Enzo Biochem Inc. v. Applera Corp.*, 780 F.3d 1149 (Fed. Cir. 2015), the Federal Circuit reversed the District Court’s infringement decision when considering the claim expression “wherein A comprises at least three carbon atoms and represents at least one component of a signaling moiety capable of producing a detectable signal” The Federal Circuit’s reasoned that the meaning of the disputed claim expression in view of the specification requires that a signaling moiety be composed of components, of which at least one component is ‘A’ in combination with the other components and “not that ‘A’ itself can be a signaling moiety.

See also *SIMO Holdings, Inc. v. Hong Kong uCloudlink Network Technology Limited* (Fed. Cir. Jan. 5, 2021).

Therefore, it seems likely that “at least one” followed by a list of items may be interpreted to modify each item in the list as a conjunctive list to require all items in the list for finding infringement.

To help avoid an unintended interpretation, patent application drafters can consider explaining the intent of using “at least one” either by defining the expression or providing examples.

U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Infinity Computer Products, Inc. v. Oki Data Americas, Inc
Aruging your Way to Indefiniteness

By: Sunil Chacko, Associate

In *Infinity Computer Products, Inc. v. Oki Data Americas, Inc.* The U.S. Court of Appeals for the Federal Circuit affirmed a district court's decision to invalidate US Patent. No. 6,894,811 ('811) and three other related patents due to indefiniteness.

Patent 6,894,811:

Patent '811 was directed to "*using a fax machine as a printer or scanner for a personal computer.*"
 Claim 1 is reproduced below:

A method of creating a scanning capability from a facsimile machine to a computer, with scanned image digital data signals transmitted through a bi-directional direct connection via a passive link between the facsimile machine and the computer, comprising the steps of:

- by-passing or isolating the facsimile machine and the computer from the public network telephone line;
- coupling the facsimile machine to the computer;
- conditioning the computer to receive digital facsimile signals representing data on a scanned document; and
- conditioning the facsimile machine to transmit digital signals representing data on a scanned document to the computer, said computer being equipped with unmodified standard protocol send receive driver communications software enabling the reception of scanned image signals from the facsimile machine, said transmitted digital facsimile signals being received directly into the computer through the bi-directional direct connection via the passive link, thereafter, said computer processing the received digital facsimile. Signals of the scanned document as needed. (Emphasis Added)

Initial Prosecution:

At issue in this case was the term "passive link". The term passive link was not originally in the application or in the parent Application No. 08/226,278 ('278). Instead, the term was introduced into the claims to overcome an anticipation rejection of US Pat. No. 5,452,106 (Perkins). Perkins was directed to using a fax machine as a scanner or printer for a computer.



U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Infinity Computer Products, Inc. v. Oki Data Americas, Inc **Aruging your Way to Indefiniteness (cont.)**

In order to overcome the rejection, the Applicant asserted that their method “creates a passive link between the facsimile machine and the computer in order to accommodate the signal transfer for printing or scanning” and amended the claim to include the term *passive link*. Additionally, the Applicant argued the claimed *passive link* transmits data directly to the I/O bust of the computer without intervening circuitry. In contrast, Perkins relied on intervening circuitry. As a result of this argument and amendment, Patent ‘811 was granted.

Ex Parte Reexamination:

Patent ‘811 was subject to an ex parte reexamination. During the reexamination, Infinity sought to antedate prior art reference US Patent 5,900,947 (‘947) by arguing priority to the ‘278 Application.

In order to antedate the Patent ‘947, Infinity attempted to show that term *passive link* was supported in the ‘278 application. Infinity, asserted that Figs. 2b-2d of ‘278 application disclosed a RJ-11 telephone cable and that the RJ-11 was a direct and passive link. However, Figs. 2b-d, depicted the use of interface circuitry similar to the Perkins reference. Infinity’s assertions were in direct contrast to the arguments they made during the initial patent prosecution.

The Federal Circuit, after reviewing the entire prosecution history of Patent ‘811, determined the term *passive link* was indefinite. Specifically, the court stated that statements related to the term *passive link* were inconsistent throughout the prosecution history. As a result, the patent was invalidated due to indefiniteness.

Implications of the Decision:

The Federal Circuit’s recent decision serves as a reminder that contradictory positions taken during prosecution can render claims indefinite. Therefore, during the course of prosecution the Applicant should take into consideration previous arguments before making claim amendments and presenting new arguments.

USPTO NEWS

**USPTO Fast-Track Appeals Pilot Program
An Update**

By: Jeremy Stroh, Partner

As reported in the Staas & Halsey New Bulletin of July 13, 2020, the United States Patent and Trademark Office (USPTO) launched a Fast-Track Appeals Pilot Program to speed up patent examination and ex parte appeals. Under the Fast-Track Appeals Pilot Program, the USPTO expected the average ex parte appeal to be decided within six months from the date a petition to request the fast-track appeal was granted.

On February 18, 2021, an update to the Fast-Track Appeals Pilot Program was provided during a “Boardside Chat” presentation given by a panel including two Administrative Patent Judges from the Patent Trial and Appeal Board (PTAB). During the presentation, preliminary results regarding the Fast-Track Appeals Pilot Program indicated the average time to decision on appeal was much shorter than six months, and was actually averaging 1.9 months. The time to decide the petition to participate in the Fast-Track Appeal Pilot Program was also only 1.5 days with virtually all petitions being granted except in those cases where the appeal had not yet passed on to the PTAB’s jurisdiction.

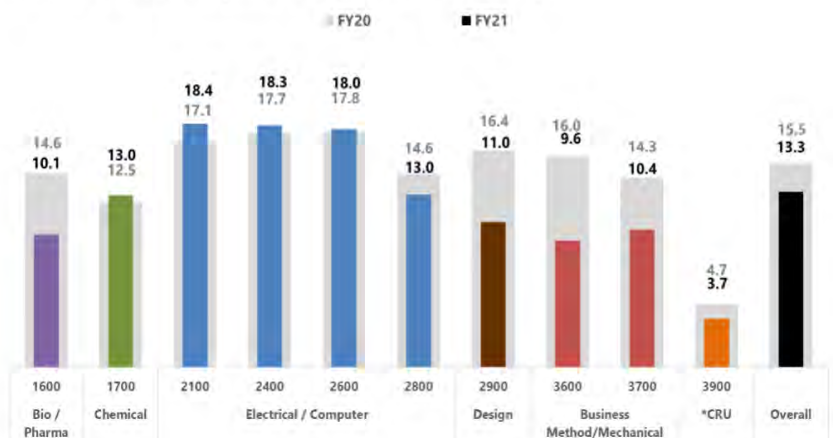
Furthermore, the panel emphasized that the Fast-Track Appeals Pilot Program was not being utilized to its full potential. That is, while the Fast-Track Appeals Pilot Program limits the number of granted petitions to about 125 per quarter, only 62 petitions were received in the first quarter and only 42 were received in the second quarter. As of March 5, 2021 (and for the quarter ending on March 31, 2021), only 35 petitions were received. Therefore, a petition to participate in the Fast-Track Appeals Pilot Program is very likely to be granted as the number of petitions received thus far has not come close to the 125-petition limit.

The panel agreed that the Fast-Track Appeals Pilot Program was working as intended by providing expedited decisions in about 1.9 months from the date that the petition was granted. This is quicker than the six-month anticipated decision time, and much faster than the typical 13-month average time to decide an appeal overall.

TC	# Petitions Filed
1600	17
1700	7
2100	10
2400	9
2600	16
2800	11
3600	22
3700	12

Pendency of decided appeals

(Dec. 2019 – Feb. 2020 compared to Dec. 2020 – Feb. 2021)



USPTO NEWS

**USPTO Fast-Track Appeals Pilot Program
An Update (*cont.*)**

Statistics from the panel's presentation (reproduced above on the left) show that most petitions are filed in Technology Centers 3600 (business method/mechanical), 1600 (bio/pharma), and 2600 (electrical/computer). These statistics appear to be reflective of the number of appeals filed (TC 3600 files the most) and a desire to expedite prosecution (TC 2600 having the second-longest pendency for appeals as shown in the chart above on the right).

Conclusion

To participate in the Fast-Track Appeals Pilot Program, a fee of \$420 must be paid and the appeal must be an ex parte appeal for which a Notice of Appeal has been filed and a PTAB Docketing Notice has been issued by the USPTO.

Applicants who wish to expedite prosecution of an application under appeal should strongly consider participating in the Fast-Track Appeals Pilot Program to have the appeal decided out of turn. Participation in the Fast-Track Appeals Pilot Program is not limited to new appeals. Therefore, pending appeals in which a docketing notice has already been issued can still file a petition to have the appeal expedited.



USPTO NEWS

**USPTO Year in Review
2020 Patent Trends**

By: Gene M. Garner II, Partner
An Nguyen, Law Clerk

In February 2020, the United States Patent and Trademark office (“USPTO”) released its annual Performance and Accountability Report for Fiscal Year 2020. Overall, the report showed a slight decrease in U.S. patent application filings in fiscal year 2020 but an increase in patent issuances across utility, design, and plant applications compared to fiscal year 2019. Additionally, the USPTO is now offering final decisions faster, with an average time of 23.3 months compared to 23.8 months in 2019. The USPTO maintained their goal of 14.8 months for average first action pendency.*

Patent Filings

	2019	2020	Δ%
Utility	619,017	603,764	-0.98
Reissue	1,096	1,064	-0.97
Plant	1,159	1,044	-0.90
Design	45,571	47,439	0.96

Patent Issuances

	2019	2020	Δ%
Utility	336,846	360,784	0.93
Reissue	554	608	0.91
Plant	1,193	1,350	0.88
Design	31,846	36,313	0.88
Total	370,423	399,055	0.93

UPR Pendency Statistics by Technology Center (in months)	Average First Action Pendency	Total Average Pendency
Tech Center 1600—Biotechnology and Organic Chemistry	13.3	22.6
Tech Center 1700—Chemical and Materials Engineering	16.8	26.9
Tech Center 2100—Computer Architecture, Software, and Information Security	16.0	26.5
Tech Center 2400—Networks, Multiplexing, Cable, and Security	12.9	23.1

USPTO NEWS

**USPTO Year in Review
2020 Patent Trends (cont.)**

Tech Center 2600—Communications	11.4	19.2
Tech Center 2800—Semiconductor, Electrical, Optical Systems, and Components	13.1	21.1
Tech Center 3600—Transportation, Construction, Agriculture, and Electronic Commerce	16.7	26.4
Tech Center 3700—Mechanical Engineering, Manufacturing, and Products	17.7	28.0
Total Utility, Plant, and Reissue Pendency	14.8	23.3

*All data comes from USPTO’s 2019 and 2020 Performance and Accountability Report, available at <https://www.uspto.gov/about-us/performance-and-planning/uspto-annual-reports>



USPTO NEWS

**USPTO Year in Review
2020 Trademark Trends**

By: Gene M. Garner II, Partner
An Nguyen, Law Clerk

In February 2020, the United States Patent and Trademark office (“USPTO”) released its annual Performance and Accountability Report for Fiscal Year 2020. Overall, the report showed an increase in U.S. trademark application filings in fiscal year 2020 but a slight decrease in trademark renewals compared to fiscal year 2019.

U.S. Trademark Applications and Registrations for fiscal Years 2000-2020:

Year	Registration	Renewal	Section 8 Affidavit
2000	375,428	24,435	28,920
2001	296,388	24,174	33,547
2002	258,873	34,325	39,484
2003	267,218	35,210	43,151
2004	298,489	32,352	41,157
2005	323,501	39,354	47,752
2006	354,775	36,939	48,444
2007	394,368	40,786	49,241
2008	401,392	42,388	68,470
2009	352,051	43,953	65,322
2010	368,939	48,214	61,499
2011	398,667	49,000	65,771
2012	415,026	63,636	76,646
2013	433,654	74,280	93,174
2014	455,017	67,865	107,823
2015	503,889	63,981	88,486
2016	530,270	72,744	87,447
2017	594,107	79,557	92,138
2018	638,847	85,563	96,091
2019	673,233	80,526	98,234
2020	738,112	76,184	97,636

USPTO NEWS

**USPTO Year in Review
2020 Trademark Trends (cont.)**

2020's Top 10 U.S. Trademark Applicants

Rank	Company	2020
1	Walmart Apollo, L.L.C.	478
2	Amazon Technologies, Inc.	366
3	Novartis AG	318
4	Aristocrat Technologies Australia Pty Ltd.	397
5	MATTEL, Inc.	281
6	HUAWEI TECHNOLOGIES CO. Ltd.	273
7	Target Brands Inc.	245
8	Microsoft Corporation	242
9	Play'n GO Marks Ltd.	241
10	QING WUTONG CO. Ltd.	240

2020's Top 10 U.S. Trademark Applicants

Country	2019	2020	Δ%
China	76,334	102,593	0.74
Canada	17,764	16,431	-0.92
United Kingdom	16,116	15,288	-0.95
Germany	14,359	13,432	-0.94
Japan	8,779	8,671	-0.99
Australia	7,303	7,358	0.99
France	8,660	7,259	-0.84
Republic of Korea	5,649	6,557	0.86
Switzerland	6,922	6,128	-0.88
Italy	5,715	5,104	-0.89
Total	167,601	188,821	0.89

**S&H FIRM NEWS*****StaaS & Halsey LLP Has Gone Paperless!***

Since about the year 2010, our firm has maintained duplicative paper and electronic “official” files for each of our client’s matters. Effective January 1, 2020, our firm discontinued maintenance and use of our “official” paper client files, and instead relies only on our electronic official client files. This change in procedure takes advantage of advances in technology to reduce costs and improve efficiency.



S&H FIRM NEWS***Continuing Uninterrupted In View of COVID-19***

Staas & Halsey LLP (S&H) continues to monitor the rapidly changing circumstances surrounding COVID-19, the illness caused by a novel coronavirus. We have taken measures to continue to provide uninterrupted service to our clients during the COVID-19 outbreak in the USA and other countries.

Beginning Monday, March 16th 2020, we implemented the S&H business continuity plan that allows our attorneys and staff to work remotely when necessary. By adopting a document management system ten years ago and going completely paperless in early 2020, the transition to remote working has been relatively smooth.

The S&H remote work system for employees uses an encrypted tunnel to provide connectivity to the S&H servers storing the S&H document and docketing management software, and access to email servers. Staas & Halsey is in compliance with the UK Data Protection Act 2018, as amended in 2019; the European Union's General Data Protection Regulation (GDPR); and the California Consumer Privacy Act (CCPA).

The above mentioned business continuity plan is anticipated to continue until further notice, and may be updated, including any updates taking into consideration recommendations of U.S. local and federal governments and the World Health Organization.

We continue to ask that communication to our firm be electronic, via e-mail, facsimile, portals, or similar means. If physical items need to be sent to Staas & Halsey LLP, please provide S&H prior notification and at least inform Docketing@s-n-h.com of any such anticipated delivery of physical items so that S&H can make arrangement for receipt of such physical items. If we normally send you packages of physical items, like paper copies of communication, please note that at times these may be delayed.

We have postponed all travel plans as a precaution based on the recommendation of the U.S. local and federal governments and the World Health Organization.

We send our best wishes and thoughts to everyone that have been affected by the COVID-19 virus and hope for a healthy tomorrow.

If you have any questions, please contact us at Docketing@s-n-h.com.

S&H FIRM NEWS



STAAS & HALSEY LLP CELEBRATES 50 YEARS in 2021

Specializing exclusively in intellectual property, Staas & Halsey LLP brings together technical and legal expertise in our commitment to provide quality legal representation.

Since 1971, we have provided clients with technical expertise and intellectual property protection.

We provide our clients with high quality and high value intellectual property protection through patent application and trademark application preparation and prosecution services before the United States Patent and Trademark Office, understand and care for our clients' concerns by developing long-term and close relationships with our clients, and provide our clients with training to understand the complexities and nuances of U.S. patent prosecution.

We thank all of our clients for being part of our journey!

STAAS



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