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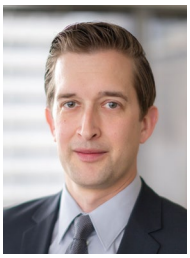
A review of developments in Intellectual Property Law

Avoiding Common IP Pitfalls: What Every Startup Needs to Know

By Emily Miao, Ph.D. and Bryan G. Helwig, Ph.D.



Startup companies often face significant risk and liability with respect to Intellectual Property (IP) on their path to success. The failure to adequately address IP issues can lead to the permanent loss of IP rights and create a litigation risk. Furthermore, insufficient or nonexistent IP protection can hamper business transactions, including seed funding, partnerships, and status as a desirable acquisition target. This article discusses common IP pitfalls and outlines steps that startups can implement to protect IP assets while reducing the risk of litigation.

A. What are IP Assets?

Conceptually, the term "intellectual property" can be thought of as creations of the mind that are given legal rights commonly associated with real or personal property and can have economic value. These property rights are generally a function of federal and/or state laws and include patents, trademarks, copyrights and trade secrets. All businesses have some form of IP that provides a competitive advantage and helps generate profits. Many companies mistakenly believe that patent protection is the only form of IP protection and ignore the value of non-patent IP. However, it is imperative that startups identify patent and non-patent related IP assets when evaluating their IP portfolio. Information describing the various forms of IP (*e.g.*, patents, trademarks, service marks, copyrights, and trade secrets) can be found on the U.S. Patent and Trademark Office website.[1]

B. Common IP Mistakes

Investors typically conduct due diligence to evaluate the strength of a startup's IP portfolio for valuation and negotiation purposes.[2] Generally, investors seek to ensure a return on their investment by identifying factors that can impede development of the startup's commercial product or service.[3] The strength of a startup's assets, including IP assets, informs valuation, influences negotiations, and significantly impacts a startup's ability to secure funding, establish partnerships and enhance acquisition. Common pitfalls that negatively affect the valuation of a startup include underestimating IP importance, a lack of confidentiality protections, failure to establish clear IP ownership and third party rights, and poorly drafted IP agreements.

1. Underestimating IP Importance and Failure to Create an IP Plan

Startups, from conception, need to determine the role of IP in their business, the IP tools that support their business

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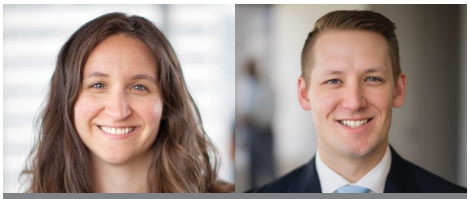

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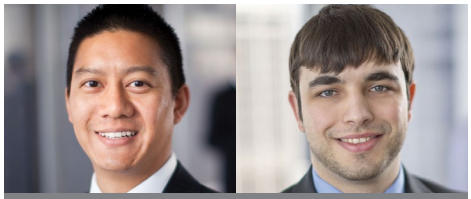

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model, and their IP strategy. In many instances, a startup's intangible assets may be the only assets and failure to fully consider IP during launch is the source of many IP missteps and oversights. In contrast, a well-structured IP strategy is a proactive step towards seed funding and avoiding loss of IP assets while minimizing the risk of third party IP infringement.

The IP plan should identify existing and future IP assets; provide a strategy for maintaining and protecting the IP assets; outline a strategy for conducting freedom-to-operate (FTO) searches; and establish an IP-related budget. The initial step of identifying existing and future IP is critical as it can help the startup develop a plan for allocation of resources and capital to support the IP assets. Importantly, the information can be cross-referenced against the startup's business and product development plans to develop, maintain, protect, and leverage IP assets. For instance, if the IP assets include trade secrets, the IP plan should include procedures to protect the information such as marking the documents, establishing check-in/out procedures, limiting access to documents, and storing the documents in a secure facility or network section.[4]

The IP strategy should also include a plan for periodic review of agreements to ensure all necessary legal IP safeguards are in place for new and departing employees, consultants, developers, and contractors.[5] Importantly, the IP plan needs to be continually reviewed and revised as the business evolves. Finally, a strategically thought out IP plan may include a business's conscious decision not to pursue registered IP rights; however, oversight resulting in failure to protect IP rights can be devastating.

2. Not Establishing Confidentiality Protections

Startups should consider a risk reward analysis before publicly disclosing confidential and sensitive IP information. For example, startups often misstep and publicly disclose patentable subject matter at investor meetings, pitch events, or on company websites prior to filing a patent application. Unfortunately, public disclosure of an invention prior to filing a patent application can limit or destroy patent rights. Public disclosure can also destroy a company's trade secrets.[6] Third-party conversations with those not under legal obligation to maintain confidentiality, a public pitch or presentation, a trade show, and publication are common examples of public disclosure. If such disclosure is necessary, the startup should file a patent application or have third parties sign a written Non-Disclosure Agreement (NDA). However, venture capitalists generally avoid signing NDAs because they deal with many startups and believe confidentiality obligations limit their contact and investment opportunities. Furthermore, while speaking at tradeshows or making a pitch, securing an NDA may not be feasible. In such instances, to avoid disclosing confidential information, the revealed information should be limited to generalities. Alternatively, a precautionary filing of a provisional patent application can protect information from any accidental disclosure that would otherwise interfere with IP protection.[7]

3. Failure to Establish Clear IP Ownership

Failure to establish IP ownership rights can be a deal breaker in business transactions. Due diligence analysis generally seeks to verify the startup's ownership rights to each piece of IP as well as determine if there are any restrictions on its use. Typically ownership issues can be averted if addressed early, sometimes even before the incorporation of the startup.

A. Startups and Current Employment

Founders of many startups continue to work for a third-party employer. In many instances, companies require that employees sign confidentiality and invention assignment agreements in which the employee agrees to assign all new ideas and inventions related to the employer's business to the employer. This is particularly problematic if the startup product or service is closely related to the employer's business as the employer may be able to claim rights to the startup's IP. Thus, it is important that founders carefully review their current employment agreements and fully understand employment obligations, including IP assignment clauses and non-compete language. Employees should also consider discussing personal projects/inventions with their employer upfront to avoid ownership issues. Generally, employer resources or company time should not be used to develop projects for the startup company without the pre-approval of an employer and without the employer's agreement not to claim ownership rights.[8]

In many instances, multiple stakeholders contribute IP to the startup. As a general rule, IP rights belong to the individual who conceived of an invention or created the work first, absent any agreement to the contrary.[9] Well-crafted written agreements between stakeholders and the startup can ensure all rights are assigned to the startup. For IP created before pre-incorporation, IP transfer via written agreement, in exchange of company shares or for money, is recommended. If co-founders are involved in the formation of the startup, a founder agreement may be important in ensuring that the startup owns the IP. Such an agreement can prevent issues with respect to a departing co-founder later claiming IP ownership.[10]

B. Startups and Independent Contractors/Employees

Startups often misconceive that hiring a contractor to create work for a business automatically gives the startup ownership rights of the work.[11] This is not always true and to ensure the startup owns all IP in all startup-funded work, the startup should have employees and independent contractors enter into "work-for-hire" and assignment

agreements that explicitly confer rights in the works to the startup.

Additionally, startups frequently hire independent contractors to create websites, software, marketing materials and prototypes for instance. Failure to implement written work-for-hire or consulting agreements with suitable IP clauses that clearly establish the startup's ownership rights to the IP prior to commissioning the contracted work can be devastating. This is particularly important if the startup plans to sublicense the work to others, make multiple copies of the work for sale, or hire others to modify the work.[12]

Startups should also have employees sign confidentiality and invention assignment agreements with clauses that clearly state their obligation to assign all developed IP to the startup. Failure to include such clauses can create ownership problems for the startup, especially if the employee leaves the company to work for a competitor or cannot be subsequently located.[13]

The agreements should state that the startup's confidential information is only for use for the benefit of the startup; require disclosure of ideas, inventions and discoveries related to the agreement or employment; and include a statement of ownership rights over ideas, inventions and discoveries. Recordable assignment of IP rights should be required to show clear ownership of inventions and other IP developed by its contractors and employees.

4. Failure to Identify Third Party IP Rights

Startups should be cognizant that IP commercialization may be blocked by a competitor who holds a patent for a technology incorporated within a product. Accordingly, startups, at an early stage, should commission a "freedom to operate" (FTO) clearance search to assess litigation risks. An FTO is performed to make sure that commercial products, marketing and use of the product, process or service does not infringe the IP rights of third parties.[14]

An FTO analysis begins by searching issued patents or pending applications and obtaining a legal opinion as to whether the product, process, or service may be considered to infringe one or more patents owned by others. Patents that limit the startup's FTO can be addressed by buying or licensing the patent, cross-licensing the patent, or "inventing around" the patented invention by altering the product or process to avoid infringement.[15]

In software development, a startup may choose to incorporate open source software into its code. However, open source licenses need to be carefully reviewed to ensure compliance with license terms. In some instances, the use of open source code in a startup product may transform the startup's proprietary code into open source software resulting in public disclosure of the proprietary code.[16]

Startups sometimes consider using third party photographs, images, or text in marketing or product support materials. In such cases, the startup should investigate if permission is required to use the material, identify the rights needed, and contact the owner for permission or a license. Startups should make sure the copyright permission or license agreement is in writing.[17]

Comprehensive trademark searches should be conducted early in the business planning process to make sure that the desired business, product, or service name does not conflict with a registered trademark. A startup that fails to conduct a proper trademark search risks being sued and may need to rebrand itself after launch and incur the tangible and intangible costs associated with rebranding.[18]

Businesses need broad awareness when hiring new employees, especially those that may have knowledge of competitor's trade secrets. New employee agreements should include clauses that prohibit employees from transferring or using proprietary information or materials from previous employers. The startup should also verify that the new hire is not subject to any binding non-compete agreements from former employers.[19]

In dealing with third party rights, startups are well-advised to consider their options at an early stage. In some cases, minor product or service changes, payment of a small licensing fee to the patent or copyright owner, and/or changing potentially problematic trademarks early on and implementing careful employee hiring practices may be sufficient to avoid future disputes and can improve a startup's chances of attracting business partners and investors to support its business development plans.

5. Using Poorly Drafted IP-Related Agreements or No Agreements at All

The valuation of a startup is based on IP as well as agreements with IP clauses. Examples include employment, consulting, funding, collaboration, settlement, licensing, research, and material transfer agreements. Thus, poorly drafted or non-existent IP-related agreements can be problematic for a startup. Because of a lack sufficient funding, many startups attempt to save legal expenses by using template IP-related agreements from a variety of non-professional sources, including the internet. However, such agreements can fail to include clauses that adequately protect the startup's interest and in many cases, can include clauses that jeopardize a startup's IP. Thus, when using IP-related agreement templates, the startups should have such agreements vetted by professionals.

Many IP-related agreements, particularly research agreements, generally include confidentiality, publication, and IP clauses. The startup should review confidentiality and publication clauses to ensure that confidential information, including trade secret information, is protected from disclosure and that the startup has the right to review manuscripts and other materials containing confidential information before publication. With respect to the IP clauses, the startup should make sure the language allows for retaining its own IP and for protecting jointly developed IP.

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Guidelines for Drafting and Prosecuting U.S. Design Patents

By Jori R. Fuller and Jordan J. Pringle

Introduction

In the wake of the ongoing *Apple v. Samsung* saga, design patents are becoming increasingly popular as an additional or alternative mechanism to protect inventions. This article focuses on drafting and prosecuting U.S. design patents, including a list of best practices and things to keep in mind when securing design patent protection for an ornamental design.

U.S. design patents cover the ornamental design of an object having practical utility. "In a design patent application, the subject matter which is claimed is the design embodied in or applied to an article of manufacture (or portion thereof) and not the article itself."[1] "Since a design is manifested in appearance, the subject matter of a design patent application may relate to the configuration or shape of an article, to the surface ornamentation applied to an article, or to the combination of configuration and surface ornamentation."[2] A "[d]esign is inseparable from the article to which it is applied and cannot exist alone merely as a scheme of surface ornamentation. It must be a definite, preconceived thing, capable of reproduction and not merely the chance result of a method."[3] In contrast to "a 'utility patent' [that] protects the way an article is used and works, . . . a 'design patent' protects the way an article looks."[4]

In addition to providing separate legal protection, design patents provide a number of advantages when compared to U.S. utility patents. First, design patents have a higher allowance rate. Through July of the fiscal year 2018, the allowance rate for U.S. design patent applications was 84%, compared to an allowance rate of 53.5% for U.S. utility patent applications.[5] Second, design patents have a faster time to final resolution. Through July of the fiscal year 2018, the time to final disposition for U.S. design patents was 19 months, compared to a time to final disposition of 24.1 months for U.S. utility patent applications.[6] Finally, design applications are typically less than half the cost of utility applications due to their expedited prosecution and the limited specification required in design patent applications.

As such, many innovators may find design patent protection an appealing option to provide additional protection for an innovative article of manufacture. Below are some guidelines to follow when preparing a U.S. design patent application.

1. Know the Subject Matter Qualifications

A design patent protects the visual ornamental characteristics of an invention. A common misconception is that if there is any utility to the invention, a design patent is not available to cover the subject matter of that invention. However, this is not always the case. If the product is functional, but also includes features that are purely ornamental, a design patent may be obtained on those specific ornamental features. The question to ask is: what is unique? Is it the look of the invention, or only the function? If the design of the invention is dictated by function and lacks ornamentality, then a design patent would not be appropriate. However, if only the look of the invention is unique, or if both the look and function are unique, then a design patent may be appropriate.

2. Drawing Quality is Key

As mentioned above, design patents protect only the ornamental characteristics of the design, which are the features shown in solid lines in the figures of the design patent application. Therefore, good quality drawings are essential, as they define the bounds of what exactly is protected. The design patent Examiner will require good quality drawings in order to grant the patent, but the quality of the drawings will also be important down the road if and when the scope of the patent is determined and the particular design being protected is interpreted. Use of a draftsperson that is familiar with the drawing requirements associated with design applications is highly recommended.[7]

3. Figure Views Should be Consistent

Many rejections received by applicants for design patents involve inconsistencies in the drawings. Design patents require a sufficient number of views to completely disclose the appearance of the invention.[8] Most design patents require seven (7) views of the invention – front, rear, top, bottom, right side, left side, and at least one perspective view. These views must be consistent with each other so a full understanding of the design can be reached. Elements shown in each figure should be shown in all others, assuming that the element can be seen in that particular view. Solid and broken lines should be consistent as well.

In short, design patents should be considered to provide an alternative or additional means of protection for an invention, and generally have a lower cost, higher allowance rate, and faster timeline than utility applications.

4. Use of Solid vs. Broken (Phantom) Lines

As discussed above, the solid lines in the figures of a design patent application function to define the scope of the invention. Broken (sometimes called phantom) lines may be used to show the environment in which the article is used, but do not form a part of the invention.[9] Therefore, if a product includes all the features shown in solid lines in a design patent, but not the features shown in broken lines, that product still infringes that design patent. Similarly, if a prior art reference shows the features in solid lines but not the broken lines of a design, that

prior art reference can still anticipate the design patent application. An application that includes broken lines should include a paragraph in the specification indicating that the broken lines are for illustrative purposes only and form no part of the claimed design.[10]

In addition, broken lines may be used to broaden the scope of the design patent in a continuation application. For example, a continuation application may convert originally-disclosed solid line structure to broken lines.[11] Since it is the solid lines that function to define the scope of the invention, replacing solid lines with broken lines necessarily broadens the scope of the design patent.

5. Include Additional Embodiments

Similar concepts with slightly different modifications, such as certain features being shown in solid and broken lines, should be filed in the same application. The Patent Office may or may not issue a restriction requirement, depending on how closely related the designs are, and further depending upon the particular Examiner assigned to your application.[12] Including different embodiments allows different levels of protection for the same invention. There is no downside to including embodiments of different scope in the same application. The Patent Office will issue a restriction if warranted, and subsequent divisional applications can be filed which are directed to the restricted embodiments. Alternatively, an Appendix including additional or related embodiments may be filed in the application. The Appendix will serve as support for future drawing amendments or continuation applications and should be canceled by the Examiner upon allowance of the application.

Conclusion

In short, design patents should be considered to provide an alternative or additional means of protection for an invention, and generally have a lower cost, higher allowance rate, and faster timeline than utility applications. The guidelines outlined above should be considered when preparing an application for an ornamental design.

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Endnotes

1 Manual of Patent Examining Procedure (MPEP) § 1502 (citing Ex parte Cady, 1916 C.D. 62, 232 O.G. 621 (Comm'r Pat. 1916)).
2 *Id.*
3 *Id.*
4 *Id.; compare* 35 U.S.C. § 101 with 35 U.S.C. § 171.
5 *Data Visualization Center*, USPTO, https://www.uspto.gov/dashboards/patents/main.dashxml (last visited Aug. 20, 2018).
6 *Id.*
7 The Patent Office's Design Patent Application Guide, available at https://www.uspto.gov/patents-getting-started/patent-basics/types-patent-applications/design-patent-application-guide, provides such guidelines for drawings along with other additional requirements for U.S. design patent applications.
8 *See* MPEP § 1503.02.
9 *Id.*
10 *Id.*
11 *See* MPEP § 1504.04, subsection I.B.
12 *See* MPEP § 1504.05.

Patenting Repurposed Drugs

By John E. Conour, Ph.D.

Even with billions of dollars of funding and the cumulative knowledge and experience of over a hundred years of experimental pharmacology, *de novo* discovery of effective and safe therapeutics remains a costly and risky endeavor. The number of unsuccessful attempts to obtain Food and Drug Administration (FDA) approval of drugs for specific indications is far greater than the number of successes. As a result, there is an extensive and ever growing list of "failed" drugs, most of which are ultimately abandoned by pharmaceutical companies.

More recently, failed drugs previously considered to be lost causes are being reconsidered as possible therapies for different indications than those for which they had originally been considered. Such drug "repurposing" provides researchers and clinicians with a cost-effective way to identify potential new therapies without needing to start from scratch. Many failed drugs have already established their relative safety in Phase I clinical trials, which can simplify and reduce the cost of obtaining FDA approval should a new indication be found. Drug repurposing is not limited to failed drugs but is also being considered for currently marketed drugs as well as "off patent" generic compounds to expand and extend their usefulness.

But because drug repurposing primarily concerns previously-known drugs, obtaining patent protection can be challenging. In some cases, a drug to be repurposed is still protected by a patent that can be acquired and/or in-licensed, but often the drug itself is not protected by patent. Without patent protection, commercialization of a repurposed drug (*i.e.*, maximizing the potential beneficial impact of the drug) is not realistic. This article discusses certain issues to be considered when trying to obtain new patent protection for repurposed drugs. It should be expected that each attempt to patent a repurposed drug will have its own fact-specific challenges. Accordingly, the concepts discussed here are generalized and non-exhaustive.

The foundational inquiry for determining whether a repurposed drug can be patented in the United States is to consider whether, under 35 U.S.C. § 101, the drug constitutes patentable subject matter. Section 101, in relevant part, provides: "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor …"[1] Repurposed drugs are often non-nature-based compositions of matter (*i.e.*, synthetic compounds that are not naturally occurring) that can be used in useful processes (*e.g.*, methods of treating a disease by administering to a patient in need thereof a therapeutically effective dose of a drug). Therefore, claims directed to repurposed drugs and methods of their use should not typically run afoul of § 101. Even repurposed drugs that are nature-based compositions of matter may still be patentable, for example, if recited in a method of treatment claim. Indeed, method of treatment claims reciting nature-based compositions of matter seem to be on more secure footing under § 101 in light of the recent decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals,*[2] at least because the United States Patent and Trademark Office has issued a recent memorandum to the Patent Examining Corps advising that the Patent Office intends to follow the legal reasoning in this case.[3] Nevertheless, care must be taken when drafting claims to avoid § 101 issues.

The best chances for patenting repurposed drugs occur when care is given to initial experimentation to establish the usefulness of the drugs and for identifying any unexpected properties of the drugs.

Another significant hurdle to overcome with respect to patenting repurposed drugs is 35 U.S.C. § 102. Section 102, as applied to a repurposed drug, requires that it was not previously patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before a patent application is filed to cover the repurposed drug. In other words, a claim to the repurposed drug itself must be novel, in that it must recite something not previously publicly known. Practically speaking, most composition of matter claims reciting only the repurposed drug will be excluded from patentability under § 102, because (almost by definition for a "repurposed" drug) the drug was previously known and thus its earlier public disclosure would be prior art to any subsequent patent filing. Accordingly, composition claims directed to the repurposed drug itself will likely be anticipated because they are not reciting anything new. Yet there are ways to overcome § 102 to obtain composition claims on repurposed drugs.

One useful approach for overcoming a § 102 rejection is to incorporate the repurposed drug into a composition that includes one or more other compounds to form a novel combination not previously known. Importantly, the claimed combination can be any practical combination that is novel for purposes of overcoming § 102. However, as discussed below, claims to pharmaceutical compositions that recite combinations with more than one key constituent (*e.g.,* a therapeutically effective amount of a repurposed drug and a therapeutically effective amount of a second drug) are more likely to be patentable. Additional details regarding specific amounts of drugs included in combinations or ratios between the drugs in the combination can add further grounds for finding such claims patentable over what was previously known in the prior art.

A further approach to obtaining claims directed to previously known drugs that are patentable in a § 102 context is to draft claims to novel pharmaceutical dosage forms. Pharmaceutical dosage forms can be, for example, solids, liquids, delayed or extended release forms, and/or for a specific type of administration (*e.g.,* oral, parenteral, intramuscular, etc.). Many types of variations are possible with pharmaceutical dosage forms, which lend themselves to drafting novel claims. For example, desired release characteristics and/or routes of administration may differ for the new use of the repurposed drug compared to its previous use, which would provide the basis of a novel claim.

As a final and particularly important example, a method claim reciting a repurposed drug may more easily overcome § 102

rejections. Repurposing a drug for a new indication is typically a novel use of the drug. Therefore, a method-of-use claim that recites a repurposed drug for treating a subject with the new indication should also be novel. Such method claims are particularly useful because they are difficult for competitors to design around, and they are also available in many foreign jurisdictions (though with potentially different formats).

What is often more challenging for patenting a repurposed drug is overcoming an obviousness rejection. Obviousness (or lack of inventive step) falls under 35 U.S.C. § 103, which states, in relevant part, that:

> A patent for a claimed invention may not be obtained . . . , if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.[4]

Here, the basic calculus is that if a skilled artisan (*e.g.,* a clinician or researcher in the same field of practice or study as the person seeking to repurpose a drug and with the average skill level of such clinicians or researchers) who understands the prior art would have reasonably expected the drug to be useful for the new indication, then a claim to a repurposed drug for the new indication may be obvious. Obviousness rejections of claims to repurposed drugs can be very complex and can be based on a combination of several prior art references, each teaching one or more aspects of the rejected claims.

Unfortunately, the relatively straightforward strategies for overcoming a § 102 rejection are mostly ineffective for overcoming obviousness rejections. Simple chemical combinations of repurposed drugs with other drugs that may make a novel composition are arguably obvious if they are nothing more than a routine exercise for a skilled pharmacologist. Fortunately, there are ways to overcome obviousness rejections, but they can require planning well before filing a patent application, and indeed, experiments to investigate the usefulness of a repurposed drug should be designed with obviousness rejections in mind. This is because one of the most powerful arguments against an obviousness rejection of claims directed to a repurposed drug is a showing of unexpected results.[5] In this context, a showing of unexpected results can be a presentation of scientific data (often in the patent application, but data can also be presented after filing) that, for example, show a surprising effect of a drug that would not have been expected based on what was known at the time. Examples of unexpected results can include that a drug surprisingly works as intended for a new indication, or that a drug works at the dose used (*e.g.,* a surprisingly low dose), or that a combination of drugs demonstrates synergy when used together (their combined effect being greater than each drug acting alone), among others.[6] Another powerful example of unexpected results is the discovery that the drug acts via a different target or has a different mechanism of action for the new use than for its previous use. Such examples of unexpected results can overcome obviousness rejections for claims directed to method of use, or pharmaceutical dosage forms, or pharmaceutical compositions comprising a combination of drugs, respectively. Therefore, care should be given to experimental design and the types of data that are collected in support of such evidence of non-obviousness.

Finally, a patent for a repurposed drug must satisfy 35 U.S.C. § 112, which requires that a patent application include:

> [A] written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.[7]

Section 112 also requires an application to have one or more claims "particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."[8] Basically, § 112 requires that, at the time of filing, the written description must enable a skilled artisan to replicate the invention (much like a scientific paper should enable a researcher to replicate the experiments and data presented in the paper) and that the claims must be fully supported by the written description.

Careful patent application planning and drafting can avoid or overcome § 112 rejections. At a minimum, literal support for each claim should be provided, examples of various embodiments of the invention described (*e.g.,* the repurposed drugs and indication, possible drug substitutions and/or derivatives, dosing amounts, dosage forms, excipients, dosing regimens, methods of treatment, etc.), and experimental data establishing drug effectiveness included. The written description should also be drafted with sufficient detail and distinct variations of the invention to permit claim amendments that can dispose of a prior art rejection (under either § 102 or 103). Indeed, all important details and variations of the invention envisioned must be included before filing because § 112 prohibits addition of "new matter" after filing.

In conclusion, patent protection is possible for previously known drugs being repurposed for new indications. The best chances for patenting repurposed drugs occur when care is given to initial experimentation to establish the usefulness of the drugs and for identifying any unexpected properties of the drugs. By combining robust invention disclosures with thoughtful and detailed application preparation, patent applications directed to repurposed drugs will be better prepared to successfully navigate the rigors of the Patent Office.

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Endnotes

1 35 U.S.C. § 101.
2 887 F.3d 1117 (Fed. Cir. 2018).
3 *See* Memorandum from Robert W. Bahr, Deputy Comm'r for Patent Examination Policy, to Patent Examining Corps (Jun. 7, 2018), *available at* https://www.uspto.gov/sites/default/files/documents/memo-vanda-20180607.PDF.
4 35 U.S.C. § 103.
5 Other important objective evidence of non-obviousness, also known as "secondary considerations," includes evidence of commercial success, long-felt but unsolved needs, and failure of others. *See Graham v. John Deere Co. of Kansas City,* 383 U.S. 1, 17 (1966).
6 *See* Manual of Patent Examining Procedure §§ 716.02, 2145.
7 35 U.S.C. § 112(a).
8 *Id.* § 112(b).

Claiming Artificial Intelligence: AI-related Patent Filing Trends and Practice Tips

By Aaron V. Gin, Ph.D., Michael Krasniansky and Alexandra E. MacKenzie

The field of artificial intelligence (AI) has progressed rapidly over the last few decades, resulting in billions of people using AI of some form or another in their daily lives.[1] Such widespread adoption of the technology has prompted experts to suggest that the AI market could grow to as large as $15.7 trillion within the next two decades.[2] Accordingly, rewards clearly await innovators who can invent, build, sell, license, or otherwise leverage AI-related technologies. However, in light of *Alice Corp. Pty. Ltd. v. CLS Bank Int'l* and other more recent developments with regard to patentable subject matter, individual inventors and companies alike may be uncertain how to secure AI-related intellectual property (IP) assets.[3]

Here, the authors utilize various patent search and analytical tools, including Google Advanced Patent Search and Juristat, to obtain quantitative information on published AI-related patent filings. Based on such data, this article illustrates interesting trends in global patent filings, art unit assignment by claim term usage, and recent outcomes for AI-related patent applications, all of which may assist patent practitioners develop effective strategies for protecting innovations in this burgeoning technology area.

First, research indicates, perhaps as expected, that AI-related patent application filings have been increasing throughout the world at growing annualized rates. Figure 1 illustrates the number of AI-related patent application filings in various jurisdictions between the years 2006 and 2016.[4]

Notably, in 2016, AI-related patent application filings in China outpaced those of other popular jurisdictions, including the United States (U.S.), Patent Cooperation Treaty (PCT), Europe, Japan, and Korea. Other reports confirm this trend continuing through at least 2017.[5] The recent trend of increased funding for Chinese AI startups might explain this growth; those startups reportedly received nearly 50% of total global AI startup funds in 2017.[6]

While China is becoming a leader in the AI patent space, the U.S. has also recently seen tremendous growth in this technology area. For example, in 2016, applicants filed 9,605 AI-related patent applications in the U.S., a decade-over-decade increase of almost 500%.[7]

Second, research suggests that those seeking AI patent protection in the U.S. should carefully assess the particular claim language used to describe their inventions, as different AI related claim terms could lead to vastly different patent examination outcomes. More specifically, the U.S. Patent and Trademark Office (USPTO) assigns each U.S. patent application to one of many art units, which are organizational units of patent examiners. Each USPTO art unit is responsible for a set of technology subclasses in the U.S. Patent Classification System (USPC). According to the USPTO, classification of "invention information" for U.S. patent documents is mandatory, and such invention information "is almost always in the claims."[8] Therefore, the USPTO considers claim language to be a key factor when assigning an application to an art unit.

In this regard, different art units may have different examination outcomes, such as with respect to application allowance rates, examination periods, and types of rejections issued. Consequently, applicants may find it worthwhile to evaluate the relationship between common AI-related claim terms and art unit assignments. Table 1 illustrates the most popular USPTO art unit assignments for U.S. patent applications that recite various AI-related claim terms.[9]

As shown, for each claim term, the five most-popular art units are ordered from top to bottom according to the number of patent applications assigned thereto that include the claim term at issue. For example, patent applications including the claim term "artificial intelligence" were most likely to be assigned to art unit 2129.[10] Generally, this result is expected, as the art unit 2129 examines patent applications related to "Miscellaneous Computer Applications."

However, a review of Table 1 indicates that use of certain AI-related claim terms could lead to some unexpected results. For example, patent applications that include the terms "regression" or "clustering" are most commonly assigned to the art unit 1631, which examines patent applications related to "Molecular Biology, Bioinformatics, Nucleic Acids, Recombinant DNA and RNA, Gene Regulation, Nucleic Acid Amplification, Animals and Plants, Combinatorial/ Computational Chemistry".[11] This result could stem from frequent use of the terms "regression" or "clustering" in the fields of biology and chemistry, or may be due to other reasons. However, in any case, those seeking AI patent protection in the U.S. should consider the results in Table 1, in an effort to avoid assignment to unintended art units.

Furthermore, in addition to evaluating the relationship between common AI-related claim terms and art unit assignments, it is beneficial to review the historical examination outcomes for those art units. This way, those seeking AI-related patent protection in the U.S. may be able to adjust their claim term usage in an effort to obtain more favorable examination outcomes. For example, applicants could try to have their applications assigned to an art unit that has, on average, a higher historical allowance rate and/or a faster time to allowance.

Figure 1: Number of AI-related Patent Applications Filed by Year and Jurisdiction

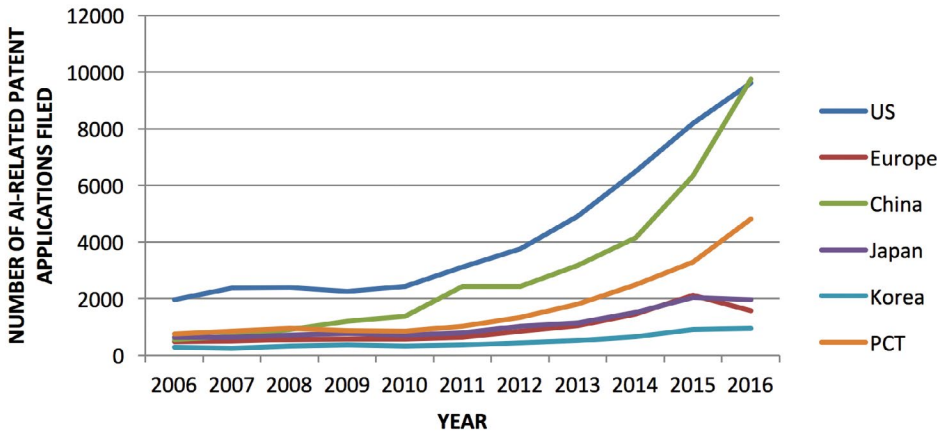

Table 1: Popular USPTO Art Unit Assignments By AI-related Claim Term

Artificial Intelligence	Machine Learning	Neural Network	Deep Learning	Supervised Learning
2129	2122	2129	2122	2122
2122	2129	2122	2669	2129
2121	1631	2121	2666	1631
3714	2665	2624	2129	2665
1631	2667	2308	2665	3664
Unsupervised Learning	**Natural Language Processing**	**Reinforcement Learning**	**Decision Tree**	**Classification**
2122	2659	2122	2129	2624
2129	2657	2129	2122	2129
2665	2122	3623	1631	2665
2624	2129	2121	2121	1631
2121	2626	3664	2626	2122
Regression	**Algorithm**	**Clustering**	**Training Data**	**Structured Data**
1631	2624	1631	2129	2162
2857	2611	2624	2122	2168
2129	1631	2129	2626	2161
2122	2129	2665	2624	2163
2863	2665	2122	2665	2164
Unstructured Data	**Heuristic**	**Model**	**Pattern Recognition**	**Computer Vision**
2129	2129	2123	2624	2624
2163	2825	2128	2129	2665
2165	2122	2624	2606	2666
2168	3623	2129	1631	2668
2162	1631	2857	2665	2667

Table 2 includes relevant outcome-based statistics for the five most common art units associated with the claim terms shown in Table 1.[12]

Table 2 indicates that art unit 2129 is not only the most common art unit associated with the AI-related claim terms in Table 1, but it is also one of the more favorable art units in terms of patent prosecution outcomes. From among the top five art units listed in Table 2, art unit 2129 has the highest allowance rate and the shortest average time from filing to allowance. Additionally, although art unit 2129 may not seem to have the lowest rejection percentages, especially in comparison to art unit 2122, the average number of office actions of 1.5 indicates that, in many cases, the prosecution phase in art unit 2129 may be relatively short.

On the other hand, research indicates that art unit 1631 is historically the least favorable art unit among those listed in Table 2. Namely, among the top five art units, art unit 1631 has the lowest allowance rate, the highest rejection percentage average, the highest average number of office actions, and the longest average time to allowance.

Table 2 illustrates other stark differences between art units 2129 and 1631. First, a review of the rejection statistics (i.e., % Alice Rejections, % 101 Rejections, % 102 Rejections, and % 103 Rejections) indicates that examiners in art unit 1631 issue, on average, 8% more rejections than art unit 2129 in each rejection type. Perhaps more significantly, examiners in art unit 1631 issue 22.62% more Alice rejections than those in art unit 2129 and 10.92% more 101 rejections than those in art unit 2129. The difference in Alice rejections is important to note, as Alice-type rejections are common for software patents.[13]

Significant differences between art units 2129 and 1631 also exist with respect to the average number of office actions and time to allowance. In particular, patent applications assigned to art unit 2129 receive about 1.5 office actions on average. This indicates that art unit 2129 may issue perhaps one or two office actions, and could issue a notice of allowance without even issuing a final rejection. Contrast this with the average of 3.4 office actions issued by art unit 1631, more than twice that of art unit 2129. Such data indicate that applicants having applications assigned to art unit 1631 may end up filing at least one request for continued examination (RCE). Finally, patent applications in art unit 1631 take more than 14 months longer to be allowed than those of art unit 2129. As such, not only is it much less likely for a patent application to be allowed if assigned to art unit 1631, but the likelihood of an RCE may significantly increase the costs and length of patent prosecution.

Table 2: Patent Prosecution Outcomes for the Five Most-Common AI-related Art Units

Art Unit	Allowance Rate	% Alice Rejections	% 101 Rejections	%102 Rejections	%103 Rejections	Average # OA	Filing to first office action (months)	Filing to Allowance (months)
2129	83%	4.58%	38.40%	45.96%	41.37%	1.5	25.9	34.2
2624	79%	0.45%	32.24%	42.52%	51.12%	1.6	32.9	42
2128	70%	22%	43.68%	49.44%	50.73%	2.1	29.4	44
2122	77%	9%	22.67%	27.83%	37.85%	1.6	25.9	35.9
1631	39%	27.20%	49.32%	40.02%	45.69%	3.4	24.9	48.7

In conclusion, research involving publicly available patent publication records confirms that AI innovation is expanding rapidly throughout the world, particularly in China. In the United States, AI-related patent applications are being assigned to a relatively small set of examination art units, based, in large part, on claim language. The vastly different outcomes across these art units should prompt patent practitioners to think carefully – before filing – about the specific claim terms recited in their patent applications. Such considerations could result in better applicant outcomes, including higher allowance rates and faster, more cost-effective patent prosecution.

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Endnotes

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3 *See Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014).
4 The authors obtained the data using Google Advanced Patent Search on June 4, 2018. With respect to Figure 1, an AI-related patent application was defined as any patent application that included the keywords "artificial intelligence" and/or "machine learning."
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8 *Overview of the U.S. Patent Classification System (USPC)*, USPTO (Dec. 2012), https://www.uspto.gov/sites/default/files/patents/resources/classification/overview.pdf.
9 Information in Table 1 is based on data the authors obtained from Juristat, a patent analytics platform, on June 6, 2018 and June 14, 2018. The top five art units were determined by summing the number of applications in each art unit from the twenty claim terms shown in Table 1. Art unit 2129 had the most applications appearing at 7,472, and art unit1631 was fifth at 3,782.
10 *TC 2100 Management Roster*, USPTO, https://www.uspto.gov/patent/contact-patents/tc-2100-management-roster (last visited Aug. 9, 2018).
11 *TC 1600 Management Roster*, USPTO, https://www.uspto.gov/patent/contact-patents/tc-1600-management-roster (last visited Aug. 9, 2018).
12 Table 2 indicates (on a per art unit basis): the allowance rate, the percentage of applications given Alice, 101, 102, and 103 rejections, the average number of office actions, the average time from filing to the first office action, and the average time to allowance. "Alice Rejections" are § 101 rejections that cite *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*.
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(continued from page 3)

Furthermore, with respect to patent license agreements involving a third party licensor, startups need to make sure that the license agreement provides all the rights needed to commercialize the licensed technology, includes future improvements to the technology, and retains the right to sublicense the technology. The agreement should also have a sufficient termination clause in the event the startup needs to opt-out of the agreement.

The agreement should also specify the relevant field of use and possibly other fields for future expansion. Importantly, the startup should review patents to ensure that the commercialized product materials, methods, and tools are properly claimed with patent life remaining. This will most likely require review by an IP attorney.

C. Conclusion

The process of bringing a new startup business to life to launching new products to the marketplace can be an exciting time. However, many startups are so focused on bringing a new product or service to market that they fail to take the necessary steps to protect the associated IP. Failure to put an IP plan in place can cripple valuation and expose the startup to potential third party infringement risk. In contrast, startups can protect and exploit their IP assets to build value and revenue by developing an IP plan as part of their conception, creating an action plan to protect IP assets including protection of confidential information, securing ownership rights to the IP, conducting freedom-to-operate searches, and ensuring properly drafted IP-related agreements are in place.

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Endnotes

1 A) For more information from the USPTO regarding patents, trademarks, and copyrights, see *What Are Patents, Trademarks, Servicemarks, and Copyrights?,* USPTO (Oct. 2015), https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-2. B) For additional resources for learning about the difference between patents, trademarks, and copyrights, see *Basic Facts: Trademarks, Patents, and Copyrights,* USPTO (Apr. 27, 2017), https://www.uspto.gov/learning-and-resources/uspto-videos/trademarks/basic-facts-trademarks-patents-and-copyrights. Trade secrets provide an alternative form of protection and can be an important IP asset for startups since they are cost effective relative to patents. C) Trade secrets derive value through secrecy and last for as long as the trade secret maintains its confidential status. No registration is required for trade secrets but reasonable efforts to maintain secrecy are required. For a discussion of trade secret policy, including an in-depth background and video, see *Trade Secret Policy,* USPTO https://www.uspto.gov/patents-getting-started/international-protection/trade-secret-policy (last modified Jul. 11, 2018) [hereinafter *"Trade Secret Policy"*].

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19 *See* Rich, *supra* note 13.

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