Foreign Priority Applications in the USPTO:
Making a Priority of the Priority Application

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Introduction

Hard lessons and expensive lessons are often learned during substantive examination of a patent application. Some of these lessons might be avoided, or at least minimized, if only something different had happened when the application was filed or drafted. What can complicate matters, is when a patent application was originally drafted by another practitioner in another language for priority filing in another country.

One aspect of this paper addresses what might be done to increase the likelihood of success for patent applications in the USPTO that claim foreign priority. The United States is certainly among the most desirable destinations for an increasing number of foreign priority patent applications, but this is not a one way street. For this reason, comments in this paper also explore what might be done to increase the likelihood of success for US priority applications being filed in patent offices around the world.

Draft Once File Everywhere

A draft-once-file-everywhere priority application means something different for each applicant and each technology involved. For some applicant’s only two or three countries are of interest. This is sometimes an easier situation than for other applicants who are interested in ten or more countries. The idea is to construct an optimal

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1 This paper contains comments corresponding to a panel discussion titled Tips and Pitfalls for Foreign Applicants in the USPTO at the March 10, 2015 Intellectual Property Owners Education Foundation event in Washington D.C. called Connecting the IP Community with the PTO. Mark Guetlich is Vice-chair of IPO’s International Patent Law and Practice committee and is an of counsel attorney to the Indian law firm Lakshmi Kumaran & Sridharan. Mr. Guetlich was formerly Senior Counsel for International Policy and Government Affairs for the USPTO Office of Policy & International Affairs. His corporate experience includes service as Managing Director of Patents at SAP headquarters in Walldorf, Germany, and Director of International Patents for Microsoft in Redmond, Washington. As an engineer, Mr. Guetlich was a Member of the Technical Staff in real-time operating systems development at AT&T Bell Laboratories in Denver, Colorado.

2 [http://www.fiveipoffices.org/statistics/statisticsreports.html](http://www.fiveipoffices.org/statistics/statisticsreports.html) - 2013 numbers represent an 11% increase in filings and 4% increase in granted patents over 2012 numbers among the 5 patent offices that process nearly 90% of the world’s patent applications.
framework for drafting and filing a well-planned priority application that minimizes the need for customization among the desired countries. A global framework for drafting patent applications is increasingly useful because filing plans can change quickly, sometimes due to evolving business opportunities and sometimes due to a transfer in ownership of the patent application.

A more global framework for drafting priority applications can facilitate greater consistency in producing high quality and cost effective patent portfolios. The approach establishes basic expectations and recommendations regarding the form and substance of a priority application as a baseline guide for practitioners drafting and reviewing draft applications. An essential ingredient, though, is for the framework to be flexible enough to accommodate individual drafting styles and the creativity that is appropriate for each unique application.

In-house counsel is encouraged to develop a global framework that best suits their client’s technology, portfolio interests, and experience. For medium and smaller entities, outside counsel may take more of a lead in suggesting a framework best suited to the client’s needs. In any case, the framework continually evolves as patent office rules change, judicial decisions are rendered, and experience evolves.

One beneficial result from developing a framework is the deeper awareness of worldwide law and practice, and the similarities/differences among jurisdictions. Patent offices could certainly do more to harmonize law and practice. Nevertheless, differences exist, so the study of optimal frameworks is worth the effort given the heightened emphasis on high quality patents and the time and cost of obtaining and enforcing those assets.

**Patent Office Frameworks**

Formality rejections and objections could be eliminated from existence. Problems persist anyway, and can turn an otherwise routine substantive examination into a difficult experience because simple problems interfere with or cast doubt on the substantive message. Mistakes happen, and they occur with increased frequency under time pressure and due to translations. Establishing a framework to guide the drafting of a priority application may sound simplistic, but the up-front effort can minimize or eliminate non-substantive errors in a priority document. These problems might be
tolerable in one country but become impossible and expensive as the same problem propagates through multiple secondary filings.

Patent offices are aware of the problems that can result from differences in law and practice. The Common Application Format (CAF)\(^3\) was one effort to address basic differences through a uniformly acceptable framework for patent application documents. The CAF was introduced in November 2007 by the Trilateral Offices\(^4\) in cooperation with the Industry Trilateral users group.\(^5\) The purpose of CAF was to rationalize the divergent format requirements among the three offices. The CAF was based in part on the standard Patent Cooperation Treaty (PCT) application format, and was agreed upon as an acceptable format for applications filed in the Trilateral Offices.

At the time of its creation, the CAF anticipated the harmonizing impact of the Patent Law Treaty (PLT) requirements, although the Offices had yet to adopt the PLT. Now, with the America Invents Act (AIA) and the PLT in force in the United States,\(^6\) and a new IP5\(^7\) set of offices are working in cooperation, it may be time to revisit the CAF format. In the meantime, the CAF is a useful starting point to develop a tailored framework in combination with experience from day-to-day practice before the world’s patent offices.

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\(^3\) [http://www.trilateral.net/projects/pct/CAF.html](http://www.trilateral.net/projects/pct/CAF.html)

\(^4\) A cooperative working relationship formed in October 1983 by the three patent offices that together were processing the majority of worldwide Paris Convention and PCT patent applications. The Offices included Japan Patent Office (JPO), European Patent Office (EPO), and United States Patent & Trademark Office (USPTO). See [http://www.trilateral.net/index.html](http://www.trilateral.net/index.html).

\(^5\) The advisory role of the Industry Trilateral users was formally recognized by the Trilateral Offices in 2008. The Industry Trilateral users are made up of delegates from the independent Non-Governmental Organizations from each region, namely the Japan Intellectual Property (owners) Association (JIPA), Business Europe, the American Intellectual Property Law Association (AIPLA) and the Intellectual Property Owners Association (IPO). The Industry Trilateral Users continue to meet approximately twice each year in the margins of the Trilateral Office meetings. The user group monitors progress and provides user-perspective input on patent office projects and initiatives, and meets with the Trilateral Offices to share comments and put forth suggestions and substantive input on recommended projects and improvements that benefit users of the patent system and patent office’s alike.


\(^7\) Created in 2008, the IP5 offices include the Korean Intellectual Property Office (KIPO), State Intellectual Property Office of the People’s Republic of China (SIPO), Japan Patent Office (JPO), European Patent Office (EPO), and United States Patent & Trademark Office (USPTO). The IP5 cooperation expanded on the concept of the Trilateral Office cooperation now that the IP5 offices process more than 90 percent of the worldwide patent applications including PCT applications. See [http://www.fiveipoffices.org/index.html](http://www.fiveipoffices.org/index.html).
Common Application Format Specifics

Sections recommended in the CAF are listed below. Be aware that this is an aging format that predates the IP5, but it is a useful starting point in developing a tailored format for a specific client that pursues patents in multiple countries.

Mandatory section titles are shown in bold text. Section titles for optional material are shown in non-bold text and are to be used where corresponding information is present or desirable in the application. The section headings and the order of the headings were determined by the Trilateral Offices.

In the written description:

- **Title of Invention** or **Title**
- **Technical Field** or **Field**
- **Background Art** or **Background**
- **Summary of Invention** or **Summary**
  - Technical Problem
  - Solution to Problem
  - Advantageous Effects of Invention
- **Brief Description of Drawings**
- **Description of Embodiments**
  - Examples
  - Industrial Applicability
  - Reference Signs List
  - Reference to Deposited Biological Material
- **Sequence Listings** **Free Text**
- **Citation List**
  - Patent Literature
  - Non Patent Literature

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9 Id. Section 1(e) “Section Titles and Order.”
In addition to the above section titles, the section titles for the rest of the application are as follows.

- **Claims**
- **Abstract**
- **Drawings**
- **Sequence Listing**

**Form, Formalities, and Substantive Content**

This section contains comments and experiences relating to the CAF section headings. An experienced practitioner from any of the trilateral jurisdictions may recognize that variations on this CAF framework have been used successfully for years. This is true and is not disputed. The recommendation, simply, is that in-house counsel and private practitioners might consider the CAF framework and the following comments in the development of a framework that conforms to their practice experience and client interests.

A first general observation that is common among practitioners with international experience, is that foreign priority patent applications inbound to the USPTO without significant changes, are often more successful in the USPTO than what US priority applications experience outbound to other jurisdictions. One reason for this, particularly in electrical, telecommunications, and computer implemented inventions generally, is that substantive examination in other countries has historically been driven by a narrower concept of patent eligibility than in the USPTO. This, however, is not entirely the experience for chemical, bio, and pharma technologies. However, more recently in the United States the America Invents Act and recent case law have narrowed the substantive gap considerably between practices among the countries.

A second general observation that is common among practitioners with international experience, is that nothing substitutes for a thorough and complete written description. However, care should be exercised to avoid including or characterizing substantive content in a priority document that would be detrimental to the substantive examination or enforcement of a granted patent in any one country. For this reason, it is generally viewed as a safer practice to comply with country specific formalities to the greatest extent possible after the priority document is on file. This keeps the priority document clean and less useful against the applicant’s own interests during substantive
examination or litigation. It is important in this practice to carefully track what content has been written in or out of the priority application, and what content requires further attention once an application is in front of each secondary filing country.

A third general observation that is common among practitioners with international experience, is that patent practice is increasingly international. This means it is important to consider conforming to the least common denominator of basic issues such as A4 document formatting, limits on the numbers of claims, and page limits even if your client’s filing target is typically only the USPTO.¹⁰ Filing plans change and the less that must be changed in a draft application to confirm with international norms, the better.

The following comments relate to various aspects of format and/or substantive content in the sections of the CAF framework. This is not necessarily an exhaustive set of comments for each section and its relationship to each country or technology. The comments are intended to share a flavor of the factors that might be considered in developing a tailored framework specific to a company or client.

**Title** – Mistakes and unnecessary words frequently find their way into something as humble as the title of a patent application. The section heading itself can be a problem. The recommended heading for the title section of a patent application is simply “Title,” not “Title of the Invention.” The same is true where the phrase “of the invention” might occur in other section headings or the text of a patent application. The phrase “of the invention” has been found to limit the scope of the claims in the United States.¹¹

A preferred title is one that reflects the invention or its underlying technology without limiting the scope or invoking a suggestion of ineligible subject matter (e.g., “business method” or “sales scheme”). Similarly, phrases such as “system and method for” add little to a title beyond additional words to translate. Keep it simple, and to facilitate this,

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¹⁰ EPC limitation made effective April 2009.
¹¹ *Honeywell v. ITT Industries* (Fed. Cir. 2006) use of ‘this invention’ or ‘of the invention’ phrases anywhere in the patent can be used to interpret and limit the scope of the claims.
an accepted norm for the length of a title is about 7 English language words.\textsuperscript{12} This word limit accommodates the rules in many countries.\textsuperscript{13}

**Technical Field** - This section is not required by all jurisdictions, and is sometimes omitted initially because it can be added by amendment after filing if necessary. If omitted for any reason, have a plan for what would be said. If included, caution is recommended to avoid any phrase that may be interpreted to limit the scope of the claims or invoke a bias against the technology.

**Abstract** - The Abstract should concisely describe the invention in terms that are consistent with the broadest claims.\textsuperscript{14} A generally accepted length for an Abstract is up to 150 words.\textsuperscript{15}

**Summary** - A summary, if included at all, is expected to be a concise, readable, overview statement that precedes the detailed description.\textsuperscript{16} Since the content is a subset of the detailed description, many practitioners view this as a section that is best added by amendment during prosecution if called for by an Examiner.

**Background** - A background section can be used to concisely summarize basic information about the state of the art prior to the invention. Regretfully, though, content in this section is more frequently than any other used against the applicant’s own interests during substantive examination and litigation. For this reason, some practitioners include very little in this section.

This section is an example of the different practices among the Offices. In EPO practice, the Examining Division routinely asks the applicant to list the closest prior art citations in the Background section. This request prompts a routine amendment at or near the end

\textsuperscript{12} PCT Rule 4.3 - The title of the invention shall be short (preferably from two to seven words when in English or translated into English) and precise. PCT rules have been approved as being compatible with the practice of EPC contracting states, so that abiding by PCT rules is a reasonable approach.

\textsuperscript{13} 37 CFR 1.72(a) Title and abstract - The title of the invention may not exceed 500 characters in length and must be as short and specific as possible. EPC Rule 41(b) – the title of the invention . . . shall clearly and concisely state the technical designation of the invention and shall exclude all fancy names.

\textsuperscript{14} 37 CFR 1.72(b); EPC Rule 47 and 57.

\textsuperscript{15} EPC Rule 47(3).

\textsuperscript{16} 37 CFR 1.73 – A brief summary of the invention indicating its nature and substance . . . should precede the detailed description. NOTE: The CFR language “should” does not mean “must.” Further, neither the EPC nor PCT expressly requires or prohibits a Summary section.
of substantive examination to insert the closest prior art citations.\textsuperscript{17} For this reason, it is desirable to keep an EPO priority application free of this prior art content at the time of initial filing because this information is detrimental in USPTO practice and litigation. This is an excellent example of content that is preferably kept out of a priority document during the priority filing, but later added by amendment as needed to satisfy requirements in a specific jurisdiction.

It is important to recognize that in most countries, any content in the Background section may be deemed prior art and an Examiner may conclude from reviewing the description of a problem in the Background that the solution would have been “obvious to try.”\textsuperscript{18} For this reason, if problems or deficiencies are described in the Background, then solutions or advantages are more safely described elsewhere in the document. This allows the solution to be sufficiently convincing and distinguished from the problem, and can be directly referenced in an arguments when defending or amending the claims.

\textbf{Drawings} – Among the sections of a patent application considered “optional,” few sections of a patent application are more beneficial to its success in nearly every jurisdiction. The benefits of including drawings far outweigh any perceived savings in time or cost by not having drawings. The visual clarity of a drawing in combination with the descriptive content of text in the detailed description can portray specifics of an embodiment or the broad scope of a basic structure reliably and with uniformity across translations. This is particularly true when language translations might otherwise alter the meaning of text in unexpected ways. The drawings anchor the text and increase the likelihood of a more uniform family of patents. Well done drawings and in generous numbers can be the best investment of time and money when preparing a priority application for success in substantive examination as well as in later license negotiations or litigation.

At minimum, every feature of an invention that is found in the Claims should ideally be represented in at least one Figure.\textsuperscript{19} This is not where the usefulness of a drawing

\textsuperscript{17} \textit{EPC Rule 42(b)} – indicate the background art which, as far as is known to the applicant, can be regarded as useful to understand the invention, draw up the European search report and examine the European patent application, and, preferably, cite the documents reflecting such art.

\textsuperscript{18} \textit{KSR Int’l CO. v. Teleflex, Inc.}, 550 U.S. 398 (2007), Supreme Court decision concerning obviousness as applied to patent claims.

\textsuperscript{19} \textit{37 CFR 1.83(a)} – The drawing in a non-provisional application must show every feature of the invention specified in the claims.
stops. Variations and alternative embodiments in a drawing, even if not expressly, add depth and clarity to a patent application when fall back positions and amendments are needed during substantive examination. Access to literal support for amendments through drawings and the accompanying text can help save a patent application from a final rejection, and can help win the day in an infringement argument.

Understanding basic form and substance requirements when creating drawings, can be among the greatest of time and cost saving steps when pursing patent rights in multiple jurisdictions. Rejections and objections and accompanying fees can be easily avoided by complying with international norms (e.g., USPTO\textsuperscript{20} and EPO\textsuperscript{21}). Rules for reference numbering,\textsuperscript{22} fonts and lines\textsuperscript{23} are simple enough and substantially uniform across jurisdictions. Minimizing the amount and orientation of text within drawings can also minimize translation costs and can avoid any need for new drawings. Some practitioners go as far as having no text at all in drawings, and instead rely on reference numbers only for the corresponding text, although the aesthetics and basic benefits of a drawing become a factor in this extreme.

Common sense approaches are recommended when considering color drawings, photographs, and screen shots as drawings. While rules exist in an increasing number of jurisdictions to allow non-line-drawings, experience repeatedly shows that the effort required to move these drawings through each patent office is not worth the time and cost or perceived benefit. This is true unless the color, or photograph, or screen shot itself is a central element of a claimed invention.

Screen shots and photographs, for example, are not editable if any office requires changes to the drawings. These formats also nearly always contain unnecessary content that can be viewed as a limitation on the scope of what is being shown. Screen shots and photographs also contain complex shading that is distracting and does not conform to patent office publication processes, electronic scanning, or photocopying procedures. Lastly, applicants that are ultimately forced to recreate a screen shot or photograph into traditional line drawings during substantive examination, often end up facing new matter rejections when the Examiner sees the line drawing compared to the original.

\textsuperscript{20} 37 CFR 1.81, 1.83, and 1.84.  
\textsuperscript{21} EPC Rule 42(e) and 46; See also PCT Rule 11 which represents rules for Drawings acceptable to all member countries.  
\textsuperscript{22} EPC Rule 49(11) – terminology and signs shall be consistent throughout the . . . patent application.  
\textsuperscript{23} EPC Rule 46(2)(a) - Drawings shall be executed without colorings in durable, black, sufficiently dense and dark uniformly thick and well-defined lines and shades.
The overwhelming recommendation of experienced practitioners is to avoid all this by creating line drawings for use in the priority document.

**Detailed Description** - The technical details in a written description are intended to describe the invention to the extent necessary and with sufficient detail to enable understanding and to disclose the technical advancement to the public.\(^{24}\) At the highest level, accuracy, readability, and thoroughness are guiding principles in any jurisdiction regardless of language. Practical experience has proven that shorter sentences, consistently used terms, and reference numbers, are characteristics of successful priority applications. This is often because the translation is less complicated. Slang language, overly technical jargon, and use of terms with multiple meanings are best avoided because they often compound misinterpretations in translation and confuse the reader.

It is worth repeating that the America Invents Act (AIA) and recent case law in the United States (e.g., Alice v. CLS Bank\(^ {25} \) etc.), have done more to align USPTO practice with the rest of the world than any other harmonization effort to date. For this reason, practitioners are recognizing that drafting practices commonly used outside the United States are increasingly useful in today’s USPTO practice. For example:

1. **Operating Environments** – For computer implemented inventions in particular, a thorough discussion of general and specific operating environments can be beneficial, along with alternative environments and variations. Among the reasons for this is to support means-plus-function claims, support subject matter eligibility arguments if needed, and to establish the groundwork for fall back positions and literal support for amendments if needed.

2. **Examples and Embodiments** - Working examples and alternative embodiments are a common practice and viewed as essential in patent drafting for jurisdictions outside the United States. This is changing in present-day USPTO practice. A recommended approach is to accompany each example, embodiment, or variation with corresponding drawing(s) and claim(s). This provides scope to the description and provides material for fall back positions during substantive examination and the literal support more frequently needed for amendments. This can also aid in the reader’s appreciation of the invention and the technical

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\(^{24}\) EPC Rule 42; See also PCT Rule 5.

\(^{25}\) Alice Corp. v. CLS Bank Int’l, 134 S. Ct. 2347 (2014)
contribution of the claimed invention whether this is needed for substantive examination, or later transactional negotiations or litigation.\textsuperscript{26}

If a ‘best mode’ or ‘preferred embodiment’ exists, it remains good practice to describe them thoroughly even if there is no requirement to identify them as such.\textsuperscript{27} Also, clearly stating the technical effect(s) or technical contribution(s) of an embodiment is recommended, whether claimed or not and whether identified as such or not. This may not be common practice historically in USPTO practice, but it is common practice outside the United States\textsuperscript{28} and is believed by some practitioners to be more and more central to success in recently evolving USPTO practice.

3. **Support for Alternative Claim Sets** - Claims in a Japanese priority application, for example, often favor means-plus-function style claims. If supported properly in the written description, these claims may be desirable in the USPTO as well as in the JPO even if the scope may be different. Nevertheless, the supporting content in the written description of a Japanese priority application would not be harmful to a secondary application in the USPTO. Support in a written description for most claim types does no harm a secondary filed application that may not include a claim of that type. For this reason, including support for all desired claim types in all desired jurisdictions is a worthwhile drafting target for a priority application. The support typically can’t be added to a written description after the priority document is filed.

**Claims** – The best written description is nothing without claims. The desire remains nevertheless to achieve the broadest claim coverage the written description will support in each jurisdiction in view of the available prior art.

Assuming the written description of a priority application contains support for all desired claim types, what remains is to complete the claim sets and supply them to the various jurisdictions for substantive examination. Finalizing country specific claim sets at the time the priority application is being drafted is a recommended practice. Numbers of claims, claim types, and multiple dependencies notwithstanding, claims sets are simply

\textsuperscript{26} EPC Rule 42(1)(c)  
\textsuperscript{27} See Sec. 15 of the Leahy-Smith America Invents Act of 2011.  
\textsuperscript{28} EPC SW Guidelines, 5.3.3, 5.3.7, and 5.3.11.
unique to each jurisdiction even though the support they rely upon is often the same or very similar.

The technical expertise and coordination needed to complete country specific claim sets may seem formidable, but it is the more cost effective and efficient approach overall. The key to making this approach cost effective and efficient is to prearrange fees, processes, and expectations in advance of the call for assistance. Larger applicants may be able to supply the necessary expertise from in-house staff. Other applicants, out of necessity or preference, may engage private practitioner experts to assist. In either case, making the necessary arrangements in advance is essential to maintain efficiency and timeliness.

One practice is to amend the various claim sets at the end of the written description so that the additional claim sets are filed as part of the priority application. The appropriate claims are later copied from within the priority application and submitted as the claims for their corresponding jurisdiction. All other claim sets not necessary in a given jurisdiction can be ignored or deleted to avoid translation costs. This approach avoids new matter rejections and removes any doubt that literal support existed for the claims. A key cost savings is that there is no need to engage a local practitioner who has never seen the application, and ask them to craft appropriate claims often under extreme time pressure.

Other practice is to hold on to the country specific claims separately from the priority application, and insert the relevant claims into the secondary filed application at the appropriate moment either before filing or by amendment while requesting examination. This approach requires its own set of coordination and some practitioners argue that it leaves the door open to new matter rejections. In any case, this approach is not procedurally different from the more common practice of drafting and submitting country specific claims immediately prior to secondary filing. As with the previous example above, the key cost savings here is that drafting the claims at the time the application is drafted, is more efficient than relearning the invention and drafting the claims a year or more later.

One final observation frequently mentioned by experienced practitioners. There is an increasing return to the fundamentals of drafting applications with clear unambiguous language and thorough support for the claims, while also pre-planning fall back positions through additional examples and varying embodiments. This discussion has been
developing as a result of practice changes in the United States due to AIA, the USPTO’s new Patent Trial and Appeal board practice, and of course judicial decisions. The days of clever claim language winning the day, or vague dodging and weaving around available support in the written description seem to no longer exist in US practice and many say never existed in Europe and Asia. For this reason, a frequently heard recommendation is that at least one straightforward strategically narrow claim is worth considering in each claim set. By strategically narrow, this means claiming the narrowest essentials of an invention in an independent claim. One reason for this is that dependent claims are often not adequately searched. Relevant art should become immediately apparent from the search results or first action on the merits of a strategically narrow independent claim. This may also help focus the applicant’s attention on appropriate next steps, including a realistic assessment of amendments needed to overcome rejections, or of the merits of continuing substantive examination at all.

Other Relevant Patent Office Initiatives

Cooperative Patent Classification\(^{29}\) - The CPC was initiated in October 2010 as a joint partnership between the USPTO and EPO to harmonize the existing European Classification System (ECLA) and the United States Patent Classification (USPC) system. This collaboration is a key step in harmonization efforts currently being undertaken through the IPS offices who are establishing plans to adopt CPC. The resulting effort is transforming search and cataloging of patents worldwide at great cost savings and efficiency for users and patent office’s internationally.

Global Dossier Initiative\(^{30}\) - The Global Dossier is a proposed set of business services intended to modernize access to international information and tools relevant to an applicant’s portfolio through a single internet portal. The same platform is being designed to improve information and tools for work sharing among participating patent offices. The service is being developed in phases with a first phase being delivered to USPTO examiners in spring 2015, and preliminary access to users (non-patent-office stakeholders) in summer 2015. The user community is encouraged to watch for further developments in this initiative.

\(^{29}\) [http://www.cooperativepatentclassification.org/index.html](http://www.cooperativepatentclassification.org/index.html)

**Closing Comments**

Pursing a patent in multiple countries is a challenging task that results in a different experience for each applicant and each technology. The idea of drafting one priority application for filing in any jurisdiction (draft-once-file-everywhere) is a concept that is made easier by tailoring a framework for drafting the priority application and for managing the secondary patent filings. This framework is often unique to each applicant and anticipates the differences in practice among the various jurisdictions for the technology involved.

The draft-once-file-everywhere framework requires up front planning and strategy, but can deliver reliable priority applications and consistent families of patents worldwide. Built into the framework is an accommodation for country specific claim sets, along with an awareness of what must be in a priority application to support each claim set in each country, and an awareness of what can be safely added later by amendment when/if needed during substantive examination.