

The Sedona Conference  
Working Group 10 on Patent Litigation Best Practices &  
Working Group 9 on Patent Damages and Remedies Commentaries

EXECUTIVE SUMMARY

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The Sedona Conference’s Working Group 10 on Patent Litigation Best Practices (WG10) and Working Group 9 on Patent Damages and Remedies (WG9) have published numerous consensus, non-partisan documents over the course of the past decade, collectively designed to move the law and practice of patent litigation forward in a reasoned and just way, consisting of:

- I. *WG10 Commentary on Patent Litigation Best Practices*
  - A. *WG10 Introductory Chapter* (July 2015 Edition)
  - B. *WG10 Case Management Issues from the Judicial Perspective Chapter* (Dec. 2015 Edition)
    1. *Section on Exceptional Case Determinations* (Oct. 2016 public comment version)
  - C. *WG10 Pleading Standards Under Iqbal/Twombly Chapter* (Oct. 2017 Edition)
  - D. *WG10 Mediation Chapter* (Apr. 2017 Edition)
  - E. *WG10 Parallel USPTO Proceedings Chapter (“Stage One”)* (Oct. 2016 Edition); *WG10 Parallel USPTO Proceedings Chapter (“Stage Two”)* (July 2017 public comment version)
  - F. *WG10 Discovery Chapter* (Dec. 2015 Edition)
  - G. *WG10 Summary Judgment Chapter* (Oct. 2015 Edition)
  - H. *WG10 Section 101 Motions on Patentable Subject Matter Chapter* (Sept. 2016 public comment version)
  - I. *WG10 Use of Experts, Daubert, and Motions in Limine Chapter* (Dec. 2015 Edition)
  - J. *WG10 Willful Infringement Chapter* (July 2020 public comment version)
  - K. *WG10 Chapter on Streamlining Lower-Value Patent Cases* (Sept. 2022 public comment version)
  - L. *WG10 Chapter on International Trade Commission Section 337 Investigations* (May 2019 Edition)
  - M. *WG10 Biopharma Litigation Chapter* (Oct. 2021 public comment version)
  - N. *WG10 Framework for Analysis of Venue Selection for Global Patent Litigation: Strategic Considerations* (Oct. 2022 public comment version)
  - O. *WG10 Framework for Analysis for the Efficient Resolution of Disputes before the Forthcoming European Unified Patent Court* (Jan. 2023 public comment version)
  - P. *WG10 & WG12 Commentary on Cross-Border Discovery in US Patent and Trade Secret Cases*
    1. “Stage One” (May 2021 public comment version)
    2. “Stage Two” (Jan. 2023 public comment version)
- II. *WG9 on Patent Damages and Remedies Commentaries*
  - A. *WG9 Commentary on Patent Reasonable Royalty Determinations* (Dec. 2016 Edition)
  - B. *WG9 Commentary on Case Management of Patent Damages and Remedies Issues* (forthcoming 2018)
    1. *Proposed Model Local Rule for Damages Contentions* (June 2017 Edition)
    2. *Patent Damages Hearings* (May 2017 public comment version)
  - C. *WG9 Framework for Analysis of Standard-Essential Patent (SEP) and Fair, Reasonable, and Non-Discriminatory (FRAND) Licensing and Royalty Issues (Stage Two)* (Jan. 2023 Edition)

The patent system was established in accordance with our Constitution to promote science and the useful arts, which should support investment in developing new technologies. At the same time, however, there is a perception among a number of people that there has been an increase in the occurrence of patent cases considered to be “abusive,” and that this has *deterred* the advancement of science. While this perception that “abusive” litigation is stifling the growth of innovation may or may not reflect reality, there is little if any dispute, that patent litigation has become extremely expensive, and that procedures need to be developed to simplify the process and control costs.

Each publication reflects the collective wisdom and experience of members of all stakeholders in the patent litigation system, including the judiciary, the plaintiff and defense bars, patent prosecutors, and in-house counsel representing various industries. The Sedona Conference’s Working Group Series output is first published in draft form and widely distributed for review, critique, and comment, including in-depth analysis at Sedona-sponsored conferences. Following this period of peer review, the draft publication is reviewed and revised by the Working Group taking into consideration what is learned during the public comment period.

Since the publication for public comment of the first Chapters of WG10’s Commentary on Patent Litigation Best Practices, WG10 has received a remarkable amount of interest in its efforts, and an increase in the number of judges, in-house lawyers, and lawyers from firms requesting to join and participate in the Working Group. Our Working Group now includes over 200 attorneys, with litigators from both the plaintiff side and defense side and in-house counsel, and over 20 federal judges.

The Sedona Conference has worked with several groups over the yearsto provide presentations relating to WG10’s efforts, including at the Third Circuit Judicial Conference, the Ninth Circuit Judicial Conference, the Federal Circuit Bar Association Bench & Bar Conference, the American Intellectual Property Law Association Annual Meeting, and the Intellectual Property Owners Association Annual Meeting.

The full text of the published documents that make up the The Sedona Conference’s Working Group 10 on Patent Litigation Best Practices (WG10) and Working Group 9 on Patent Damages and Remedies (WG9) are available free for individual download from The Sedona Conference website at <https://thesedonaconference.org/publications>.

Please send comments to [comments@sedonaconference.org](mailto:comments@sedonaconference.org). Thank you for contributing to this essential step in our ongoing efforts to move the patent law forward.

I. *WG10 Commentary on Patent Litigation Best Practices*

The Sedona Conference decided to undertake the formation of Working Group 10 (WG10) on Patent Litigation Best Practices in 2013 because it believes that the system can be significantly improved and abuses minimized by the development and utilization of procedures enhancing the efficient and cost-effective management of patent litigation.

In the process, we formed various teams, each with representation from all stakeholders in the patent litigation system, to draft Chapters for WG10's ongoing Commentary proposing best practice recommendations on a number of topics, consisting to date of:

A. *WG10 Introductory Chapter (July 2015 Edition)*

The WG10 Introductory Chapter provides the framework for the entire WG10 Commentary, with its primary goal of developing best practices and recommendations to improve the patent litigation system and to minimize abuses for the benefit of all stakeholders in the system. The July 2015 Edition of the Introductory Chapter has now been fully updated to incorporate all of the comments received in response to the August 2014 public comment version and to track the latest legislative patent reform proposals to date. To download, click [here](#).

The overarching Principle of the WG10 Commentary on Patent Litigation Best Practices is:

WG10 is developing these Best Practices to improve the system for resolving patent disputes and make it more fair and efficient. These Best Practices are to apply to and benefit all stakeholders in patent litigation, both bench and bar, and to and for all types of patent holders and accused infringers. These Best Practices should further the goals of Federal Rule of Civil Procedure 1 and “should be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding,” all to help ensure a non-frivolous patent litigation system.

The Chapter describes the factors giving rise to the high costs of patent litigation, and the recent efforts directed toward addressing this issue, including the various proposals directed at patent reform by members of the legislature and the establishment of the new post-grant proceedings at the U.S. Patent and Trademark Office by the Leahy-Smith America Invents Act in 2011.

WG10's consensus view is that the judicial branch, not the legislative branch, is best positioned to address many of the current problems with U.S. patent litigation by providing case-by-case fixes, not broad sweeping rules and regulations. The courts should be allowed a reasonable degree of latitude and discretion for managing their cases. The best avenue for addressing the concerns about the high costs of patent litigation is through initiatives such as the Patent Pilot Program, enacted in 2011 (with the goals of developing patent expertise within a select group of volunteering judges and increasing the efficiency and predictability for patent cases), and the consensus, non-partisan development of best practice recommendations such as those presented by The Sedona Conference.

B. *WG10 Case Management Issues from the Judicial Perspective Chapter (Dec. 2015 Edition)*

The WG10 Chapter on Case Management Issues from the Judicial Perspective provides Principles and Best Practice recommendations to help the courts manage patent cases. The December 2015 Edition of the Chapter has now been fully updated to incorporate all of the comments received in response to the February 2015 public comment version. The Chapter dovetails with and builds upon the Best Practices in the other Chapters of the *Commentary on Patent Litigation Best Practices*. The recommendations reflect that it is incumbent on the court—as well as attorneys and parties—to work toward a fair, cost-effective, non-burdensome, and non-frivolous patent litigation system. To download, click [here](#).

This Chapter was developed from the viewpoint of what actions would help the courts in managing the patent litigations before them. Key recommendations include:

- case management strategies for resolving disputes earlier and more efficiently;
- streamlined claim construction processes, so the courts and the parties focus on the most relevant disputes in the case;
- procedures for early exchanges of infringement and invalidity contentions and responsive contentions on each of these;
- procedures for narrowing the issues to be tried by selecting representative claims, representative products, and representative prior art;
- procedures for maximizing juror comprehension; and
- preparation of verdict forms to avoid juror confusion and inconsistent verdicts.

The other WG10 Commentary Chapters are primarily directed to the activities of litigants and what the courts should consider requiring of litigants.

The Principles that guided the development of many of the Best Practice recommendations of this Chapter focus on cooperatively narrowing the issues in dispute, complying with and attempting to enforce discovery obligations, and keeping the court timely informed of developments in the case that significantly impact the case management schedule.<sup>1</sup>

1. *Section on Exceptional Case Determinations (Sept 2016 public comment version)*

The WG10 Chapter on Case Management Issues from the Judicial Perspective supplemental Section on Exceptional Case Determinations provides Best Practice recommendations to help the courts manage this issue in light of the Supreme Court’s recent decisions lowering the standard and burden of establishing an “exceptional case” for attorney’s fee shifting determinations under 35 U.S.C. § 285 in *Octane Fitness* and *Highmark*. To download, click [here](#).

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<sup>1</sup> For the full text of the six Principles that guided the development of the Best Practice recommendations in the Case Management Issues from the Judicial Perspective Chapter, see Appendix A.

C. *WG10 Pleading Standards Under Iqbal/Twombly Chapter (October 2017 Edition)*

The WG10 Chapter on Pleading Standards Under *Iqbal/Twombly* provides Principles and Best Practice recommendations for the level of detail to be now included with the pleadings, after the Federal Judicial Conference repealed Form 18 of the Federal Rules of Civil Procedure (effective December 1, 2015) which had provided a very basic format for pleading claims of direct patent infringement. To download, click [here](#).

The Chapter addresses these issues both from the perspective of what level of detail in pleadings should meet the *Iqbal/Twombly* standard as applied to patent infringement suits, and also from the perspective of what additional information should be further encouraged from both parties to promote the efficient administration and resolution of patent disputes.

The Principles that guided the development of many of the Best Practice recommendations of this Chapter focus on balancing the need for sufficient disclosures to allow the parties to focus and narrow the issues more efficiently with the need to not allow such additional disclosure requirements to itself become the subject of significant and unnecessary motion practice.<sup>2</sup>

D. *WG10 Mediation Chapter (Apr. 2017 Edition)*

The WG10 Chapter on Patent Mediation provides Principles and Best Practice recommendations for the effective use of mediation for resolving disputed issues in patent litigation, covering topics such as: the timing of making a decision to mediate; the process of selecting a mediator; the task of preparing for a mediation; the unique issues of confidentiality in patent mediations, and the conduct of the mediation session itself. To download, click [here](#).

The drafting team approached this task from the perspective of a litigant involved in a patent litigation matter where the parties are willing to participate in a mediation. As parties' and counsel's patent mediation experiences improve, it is anticipated that they will seek out mediation with greater frequency, which will lead to a greater number of patent infringement cases being settled earlier and more economically for the greater benefit of the parties and the judiciary.

The Principles that guided the development of many of the Best Practice recommendations of this Chapter focus on the use of mediation to efficiently resolve patent disputes in whole or in part, consistent with the overall goals of the patent system and the judicial process.<sup>3</sup>

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<sup>2</sup> For the full text of the two Principles that guided the development of the Best Practice recommendations in the WG10 Pleading Standards Under *Iqbal/Twombly* Chapter, *see* Appendix A.

<sup>3</sup> For the full text of the three Principles that guided the development of the Best Practice recommendations in the WG10 Mediation Chapter, *see* Appendix A.

E. *WG10 Parallel USPTO Proceedings Chapter (“Stage One”) (Oct. 2016 Edition); WG10 Parallel USPTO Proceedings Chapter (“Stage Two”) (July 2017 public comment version)*

The WG10 Chapter on Parallel USPTO Proceedings provides Principles and Best Practice recommendations for navigating the issues that have arisen from the establishment of the new post-grant proceedings for patent invalidity determinations at the U.S. Patent and Trademark Office by the Leahy-Smith America Invents Act in 2011. It is not at all uncommon for a USPTO Patent Trial and Appeal Board (PTAB) proceeding to run concurrently with a district court litigation or a U.S. International Trade Commission (USITC) section 337 unfair trade practice proceeding involving the same patent(s), and as such there is the risk of conflicting outcomes between such parallel proceedings. A number of issues have also arisen largely from the different standards that the various forums use when construing the claims and also the different scope of discovery that each forum permits to occur. As a consequence, a number of courts have struggled with deciding various issues, e.g., of stay and subsequent estoppels. To download, click [here](#).

“Stage One” of this Chapter’s proposals were developed primarily from the perspective of district court litigation, both for practitioners and the district courts. The October 2016 Edition of the Chapter has now been fully updated to incorporate all of the comments received in response to the October 2014 public comment version.

“Stage Two” of this WG10 project expands its scope and develop recommendations directed toward improving proceedings before the PTAB and the collaborative resolution of patent disputes through both the federal courts and the PTAB working in concert, as opposed to in conflict. A new drafting team was formed in early 2015 to address issues such as: real party-in-interest and privity; presenting evidence and protecting confidentiality in PTAB Proceedings; termination after settlement; and the efficient handling of multiple parallel USPTO proceedings. The new sections were published for public comment in July 2017.

Also, as the PTAB has been developing its procedures, a number of issues have been in flux. For example, how will the PTAB decide what claims it will actually consider in the proceeding and what scope of discovery it will permit? As time and experience progress, there may well be changes to a number of aspects of the proceedings. Such changes will necessitate the WG10 drafting team to revisit this Chapter on a regular basis.

The Principles that guided the development of many of the Best Practice recommendations of this Chapter focus on the harmonization of parallel proceedings between the PTAB, ITC, and district courts and the opportunity to present evidence before the PTAB.<sup>4</sup>

F. *WG10 Discovery Chapter (Dec. 2015 Edition)*

The WG10 Chapter on Discovery sets forth Principles and Best Practice recommendations to minimize discovery abuses in patent litigation by streamlining the discovery process, requiring earlier disclosure of the most relevant materials, and requiring full disclosure of both sides’

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<sup>4</sup> For the full text of the two Principles that guided the development of the Best Practice recommendations in the Parallel USPTO Proceedings Chapter, *see* Appendix A.

contentions at a relatively early stage in the process, all to encourage meaningful and timely settlement discussions and to minimize surprise at trial. To download, click [here](#).

The Principles that guided the development of the Best Practice recommendations in this Chapter focus on proportionality, cooperation, expeditious resolution of disputes, and appropriate remedies for abuse.<sup>5</sup>

The December 2015 Edition of the Chapter has now been fully updated to incorporate all of the comments received in response to the October 2014 public comment version.

G. *WG10 Summary Judgment Chapter (Oct. 2015 Edition)*

The WG10 Chapter on Summary Judgment calls for a fundamental re-evaluation of the proper role of summary judgment motions in patent litigation. Motions for summary judgment or partial summary judgment can be useful case management tools, i.e., they can be helpful in eliminating or narrowing issues for trial where the truly relevant material facts are not in dispute. However, that utility is often lost due to the volume and the poor quality of some summary judgment motions filed today. For example, there have been a large number of cases where parties have filed numerous motions with declarations by experts for the purpose of creating a “battle of experts” on both sides; these motions are often completely inappropriate to the purpose or spirit of summary judgment motions. Parties at times have also indicated that they filed the motions to “educate” the judge or as a discovery tool to “better understand” the opposing side’s positions. Such motions are a significant burden on the courts and opposing counsel and result in a frustration and natural skepticism toward meritorious summary judgment motions. To download, click [here](#).

This Chapter provides an overarching Principle<sup>6</sup> and Best Practice recommendations encouraging courts to assume a greater gatekeeping role at an earlier stage of the case, and prevailing upon all counsel to give more consideration to merits and timing before filing any summary judgment motion. They include proposed Best Practices for cases with earlier claim construction scheduled for before the close of fact discovery, and Best Practices for cases with claim construction scheduled later in the proceedings, after the close of fact discovery.

The October 2015 Edition of the Chapter has now been fully updated to incorporate all of the comments received in response to the August 2014 public comment version.

H. *WG10 Section 101 Motions on Patentable Subject Matter Chapter (Sept. 2016 public comment version)*

The WG10 Chapter on Section 101 Motions on Patentable Subject Matter provides Principles and Best Practice recommendations for when and how courts should decide § 101 challenges in a post-*Alice Corp. v. CLS Bank Int’l* environment, and how counsel can assist the courts

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<sup>5</sup> For the full text of the six Principles that guided the development of the Best Practice recommendations in the Discovery Chapter, *see* Appendix A.

<sup>6</sup> For the full text of the Principle that guided the development of the Best Practice recommendations in the Summary Judgment Chapter, *see* Appendix A.

in addressing such challenges in a fair and efficient manner. This includes addressing important issues such as the need for claim construction prior to ruling on a § 101 patentability challenge, the use of representative claims, and the need for discovery or factual development. These Best Practices, along with the accompanying proposed standing order, are designed to assist courts in implementing optional procedures that would, if adopted, help the court and parties to identify § 101 patentability issues that can be addressed at an early stage of a case while ensuring the decision is based on sufficient evidence and adequate process. To download, click [here](#).

The Principles that guided the development of many of the Best Practice recommendations of this Chapter focus on establishing procedures requiring the parties to notify the court whether they intend to assert a § 101 patent eligibility challenge and to assist the court in evaluating the most appropriate stage of the case to decide that challenge, and the balancing the resolution of motions involving § 101 patent eligibility challenges early in the litigation and the need for sufficient evidence and adequate process.<sup>7</sup>

I. *WG10 Use of Experts, Daubert, and Motions in Limine Chapter (Dec. 2015 Edition)*

The WG10 Chapter on Use of Experts, *Daubert*, and Motions *in Limine* provides a set of recommended Principles and Best Practices to both guide and advance the ways in which experts may be fairly deployed in a manner that is the most helpful to the trier-of-fact. Perceptions and practices among district courts and the patent bar as to the most fair and effective use of experts in patent litigation continue to evolve. As many practitioners have experienced, courts vary in their treatment of expert evidence, both with respect to the timing of motions to exclude expert testimony and the way in which they permit expert testimony to be used. This Chapter identifies areas where there are apparent distinctions between or experimentation by the courts with respect to the use of experts, and offers Best Practices where appropriate. To download, click [here](#).

The Principles that guided the development of many of the Best Practice recommendations of this Chapter focus on fairly limiting the scope of expert testimony to that disclosed in the expert's Rule 26 report to encourage the full and fair disclosure of all legal positions in expert reports and to minimize surprises at trial.<sup>8</sup>

The December 2015 Edition of the Chapter has now been fully updated to incorporate all of the comments received in response to the October 2014 public comment version.

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<sup>7</sup> For the full text of the two Principles that guided the development of the Best Practice recommendations in the WG10 Section 101 Motions on Patentable Subject Matter Chapter, see Appendix A.

<sup>8</sup> For the full text of the two Principles that guided the development of many of the Best Practice recommendations in the Use of Experts, *Daubert*, and Motions *in Limine* Chapter, see Appendix A.

J. *WG10 Willful Infringement Chapter (July 2020 public comment version)*

This WG10 Chapter on Willful Infringement provides Best Practice recommendations to help the courts manage this issue in light of the Supreme Court’s *Halo* decision discarding the prior *Seagate* standard and making clear that enhanced damages are appropriate only in egregious cases.

This drafting process was a challenging one, with fundamental points of disagreement raised concerning the scope and presentation of the Supreme Court’s *Halo* decision and the subsequent applicability of the Federal Circuit’s predecessor *Read* decision and its nine nonexclusive factors for the enhancement of damages. To download, click [here](#).

K. *WG10 Chapter on Streamlining Lower-Value Patent Cases (Sept. 2022 public comment version)*

There are thousands of patent infringement lawsuits filed in the United States every year, with over 4,000 such cases filed in each of calendar years 2020 and 2021. While jury verdicts awarding damages for patent infringement in the hundreds of millions and even billions of dollars receive much attention and publicity, such cases are firmly the exception and not the rule. Instead, in the large majority of patent cases that are filed, either the patentee comes forward with a much more modest damages claim, or the jury awards a much lower amount. Working Group 10 ascertained that in the patent cases that went to trial between 2019 and 2021 where the patentee was successful in showing that at least one claim was infringed and not invalid, the amount of damages awarded was under \$15 million 74 percent of the time.

The rules and procedures that govern patent cases in the U.S. district courts, however, generally do not distinguish between patent cases where hundreds of millions of dollars are at stake and those where the amount at issue is a fraction of that amount. As a result, parties to a “lower value” patent case often expend disproportionate amounts of time and money on litigating the case. It is the consensus of Working Group 10 that patent litigants and courts would benefit from a formalized, streamlined program for resolving lower-value patent cases. It is contemplated that the program, when used, will significantly reduce both the time and cost associated with resolving patent cases where the amount at issue is in the range of \$10 million or less. As the statistics set forth above confirm, thousands of patent cases every year could be eligible for and benefit from the program.

The streamlined program may be implemented as part of a district court’s local patent rules or as an individual judge’s standing order for handling certain patent cases. A critical aspect of the program is the use of a bench trial in place of a jury trial, making use of the program optional to the parties. The program calls for significant reductions in discovery, asserted claims, defenses, asserted prior art, an early claim construction hearing, and a bench trial on liability less than a year after the complaint is filed. If the result of the bench trial is that at least one claim has been found infringed and not invalid, a streamlined damages phase would commence immediately thereafter. The entire case would be complete in a little over a year. Working Group 10 expects that the program should

cost the parties less than half of what a patent litigation typically costs today. The program should also help facilitate early settlements, as the parties will know the court's claim construction early in the case. To download, click [here](#).

L. *WG10 Chapter on International Trade Commission Section 337 Investigations (May 2019 Edition)*

The International Trade Commission (ITC) is a critical forum for those seeking to protect their intellectual property rights, particularly patent claims, against unfair imports. As overseas manufacturing has increased and injunctive relief from the federal courts has become more difficult to obtain as a result of the Supreme Court's eBay decision, ITC exclusion orders to ban infringing imports have become a more attractive option for some plaintiffs who can show the existence of a domestic industry for the products at issue. Similarly, the federal courts' willingness, unlike the ITC, to stay and defer to pending *Inter Partes* Review proceedings before the USPTO Patent and Trial and Appeal Board has made the accelerated decision-making of the ITC a more attractive alternative to slower district court proceedings. Finally, the America Invents Act's joinder rules are not an issue in Section 337 investigations, as the target of the investigation is the article being imported, with the manufacturer, distributors, downstream users, and/or importers being named, essentially, to defend against exclusion of the imported article.

While the ITC has adopted a number of common procedures, ALJs have individual rules of practice, some of which can differ significantly.

WG10 has developed principles and best practices specific to International Trade Commission Section 337 Investigations to parallel the extensive set of commentary chapters that WG10 has published for patent litigation in the federal courts. The public comment version of this commentary was published in February 2018, and has been updated in this final May 2019 version, to reflect the ITC's June 2018 amendments to its Rules governing Section 337 investigations. To download, click [here](#).

M. *WG10 Biopharma Litigation (Oct. 2021 public comment version)*

Patent litigators have always recognized differences between the biopharma and high-tech industries. The scientific unpredictability of the art and regulatory requirements to make and sell biopharma products have always set the biopharma industry apart. The vehicle for patent dispute resolution for biosimilars (large-molecule, biologic products that are made in and from living organisms) is governed by the Biologic Price Competition and Innovation Act of 2011 (BPCIA), while litigation for generic drugs (small-molecule, chemically synthesized drugs) and the Abbreviated New Drug Application (ANDA) process is set forth in the Hatch-Waxman Act of 1984. These FDA regulatory frameworks impact a number of aspects of generic drug or biosimilar patent litigation, including the protective order, access to FDA filings as well as disclosure of FDA correspondence, the timing of litigation, as well as the available remedies. These distinguish biosimilar patent litigation and generic drug patent litigation from each other and, in particular, from litigation of high-tech patents that are not subject to any comparable legislative regime.

This *Commentary on Patent Litigation Best Practices: Unique Aspects of Biopharma Patent Litigation Chapter* provides Best Practice recommendations to counsel, parties, and the courts on how to navigate the relevant statutes and unique landscape involved in biopharma litigation. This *Chapter* does not cover all aspects of biopharma patent litigation, but rather focuses primarily on those aspects where biopharma patent litigation differs from other types of patent litigation. It primarily focuses on biosimilar and generic drug patent litigation and provides case management Best Practice recommendations to permit the full and fair presentation of all substantive issues by both branded and generic/biosimilar parties. To download, click [here](#).

N. *WG10 Framework for Analysis of Venue Selection for Global Patent Litigation: Strategic Considerations (October 2022 public comment version)*

Increasingly, the most significant patent disputes are global in scope, involving multinational corporations and international activities. Because the substantive and procedural laws of relevant countries are often quite different—for example, regarding the availability of rapid injunctive relief or significant damages—parties strategize how to exploit those differences to their advantage.

The overall purpose of The Sedona Conference’s global patent litigation efforts is to provide information and guidance to counsel, parties, and the courts on how to protect jurisdictional integrity and improve the transparency of international litigation practices. To download, click [here](#).

O. *WG10 Framework for Analysis for the Efficient Resolution of Disputes before the Forthcoming European Unified Patent Court (Jan. 2023 public comment version)*

Under the soon-to-be-introduced Unified Patent Court (UPC) system with a current start date June 1, 2023, a new patent jurisdiction will arise potentially spanning the whole of the European Union (EU). The advantages are obvious: more cost-efficient litigation with the chance of obtaining an EU-wide injunction. Nevertheless, as with all new laws and regulations (let alone courts), there will be significant uncertainty around the first pending proceedings and how they will be managed by the incipient UPC. In order to mitigate these uncertainties, judges and lawyers need not only consider a whole new set of provisions and rules but also the existing case law under the different current European patent law regimes to better understand how to interpret the new rules and resolve the disputes in an efficient but also fair and equitable manner.

All stakeholders involved—patentees, defendants, practitioners, and judges—will look for guidance in the relevant provisions, but also in the body of case law formed by national court practice and decisions. There will be a joint struggle to find the best way to litigate incipient Unitary Patents (UP)—and also those “traditional” European Patents (EP) which have not been opted-out of in time—before the new UPC, keeping in mind the potential competition from national courts for shorter, more effective, and cost-efficient national procedures. To download this *Framework for Analysis for the Efficient Resolution of Disputes before the Forthcoming European Unified Patent Court*, click [here](#).

P. *WG10 & WG12 Commentary on Cross-Border Discovery in US Patent and Trade Secret Cases*

## 1. “Stage One” (May 2021 public comment version)

Increasingly, patent and trade secret disputes may be global in scope, involving multinational corporations and international activities. As a result, evidence supporting claims and defenses in resulting litigation frequently exists outside U.S. boundaries. This development in patent and trade secret litigation in U.S. courts often necessitates cross-border discovery that raises complex issues of international comity.

This *Commentary on Cross-Border Discovery in U.S. Patent and Trade Secret Cases* offers best practices to counsel, parties, and the courts on case management where cross-border discovery is necessary. In particular, the best practices address mechanisms the courts and counsel can use to plan for and streamline issues that arise from extended timelines involved with cross-border discovery, for example, letters of request under the Hague Convention on Taking Evidence Abroad.

Another focus of the *Commentary* is on access to proof issues where cross-border discovery is critical in patent and trade secret cases. The best practices address many of the comity factors that the U.S. Supreme Court identified in its seminal decision in *Société Nationale Industrielle Aerospatiale v. U.S. District Court for the Southern District of Iowa* to guide district courts when resolving disputes relating to cross-border discovery. To download, click [here](#).

## 2. “Stage Two” (Jan. 2023 public comment version)

The growing proliferation of patent and trade secret disputes rising to the level of global litigation produces significant complexities for courts and counsel in the management of cross-border discovery. This “Stage Two” *Commentary on Cross-Border Discovery in U.S. Patent and Trade Secret Cases* offers best practices that address one particularly vexing aspect of cross-border discovery—namely, the management of applications made pursuant to 28 U.S.C. § 1782 to United States district court by actual or potential litigants for evidence encompassing confidential and trade secret information to be used in a proceeding before a foreign or international tribunal.

The complexities of Section 1782 are not unique to patent and trade secret litigation. However, disputes involving intellectual property almost inevitably implicate confidential and trade secret information. While U.S. courts are well-equipped to address such issues in domestic litigation through mechanisms such as confidentiality orders, applications pursuant to Section 1782 raise significant and independent complexities by virtue of the fact that protections for confidential and trade secret information in a foreign tribunal may not align with protections typically implemented within U.S. courts. This “Stage Two” *Commentary* attempts to present mechanisms for parties raising or responding to a Section 1782 application to address these important distinctions, and bring them to the attention of the U.S. district court receiving the application. To download, click [here](#).

## II. WG9 on Patent Damages and Remedies Commentaries

The original WG9 Commentary on Patent Damages and Remedies was published for public comment in June 2014. The content of that original WG9 Commentary has been split into two stand-alone Commentaries: one entitled WG9 Commentary on Patent Reasonable Royalty Determinations; and a second entitled WG9 Commentary on Case Management of Patent Damages and Remedies Issues. In addition, WG9 has now published Stage One of its Framework for Analysis of Standard-Essential Patent (SEP) and Fair, Reasonable, and Non-Discriminatory (FRAND) Licensing and Royalty Issues.

### A. WG9 Commentary on Patent Reasonable Royalty Determinations (Dec. 2016 Edition)

Beginning in 2012, WG9 undertook an effort to revisit the *Georgia-Pacific* framework for determining a reasonable royalty with the goal of adding some much-needed clarity and predictability to this area of the patent law. WG9 recommended in its June 2014 public comment version of its Commentary on Patent Damages and Remedies a departure from the *Georgia-Pacific* framework of establishing a hypothetical negotiation at the time of first infringement, in favor of a “retrospective” approach to the hypothetical negotiation in which the hypothetical negotiation takes place at the time of trial and allows for consideration of all relevant facts and circumstances occurring up to the time of trial. After reviewing and considering comments received during the public comment process, however, it became clear that there was not WG9-wide consensus behind this approach. Although no consensus was reached, the dialogue was nevertheless beneficial for its illumination of the advantages and disadvantages of the different approaches, which are set forth in this December 2016 Edition of the WG9 Commentary on Reasonable Royalty Determinations. The Working Group is hopeful that the dialogue about alternative frameworks for the hypothetical negotiation will continue.

This Commentary further provides Principles and Best Practices regarding patent reasonable royalty determinations, addressing important issues including: the entire market value rule; apportionment; comparability of licenses; the avoidance of any “patent holdup” or “royalty stacking” effects; and noninfringing alternatives and “design arounds.”

To download, click [here](#).

### B. WG9 Commentary on Case Management of Patent Damages and Remedies Issues (forthcoming 2017)

Furthermore, in the forthcoming WG9 Commentary on Case Management of Patent Damages and Remedies Issues, WG9 will build off of the earlier work from the June 2014 WG9 Commentary on Patent Damages and Remedies and provide Principles and Best Practice recommendations for substantive and procedural damages issues regularly arising before, during, and after trial. WG9 will draft substantially revised or new sections on the following topics:

- the recent changes to the Federal Rules with respect to heightened pleadings requirements and whether, or to what extent, those requirements could/should apply to damages allegations in a complaint;

- the recent changes to the Federal Rules regarding proportionality and the impact, if any, on damages discovery;
- issues/best practices regarding injunctions in global patent disputes;
- alternatives to injunctions; and
- posttrial relief

In addition, WG9 has formed and will form stand-alone drafting subteams to draft Sections on the following topics, for eventual inclusion into the final WG9 Commentary on Case Management of Patent Damages and Remedies Issues:

1. Proposed Model Local Rule for Damages Contentions (June 2017 Edition)

In early 2015, the WG9 Steering Committee formed a subcommittee to draft a Proposed Model Local Rule for Damages Contentions, that courts could adopt in whole or in part to implement a damages contentions requirement, as will be recommended for consideration in the forthcoming *WG9 Commentary on Case Management of Patent Damages and Remedies Issues*. The June 2017 Edition of the Section has now been fully updated to incorporate all of the comments received in response to the April 2016 public comment version. To download, click [here](#).

Requiring parties to exchange a set of damages contentions in advance of both the close of fact discovery and of the filing of damages expert reports would provide greater clarity on damages theories and potential disputes earlier than tends to occur presently. This would allow for the consideration of motions related to the admissibility of damages theories and evidence during the pretrial period, rather than on the eve of trial.

WG9 appreciates that not all patent cases are alike and believes that Damages Contentions requirements should be designed with flexibility in mind so that they can, in appropriate cases, be tailored based on individual case-specific, case-management considerations.

2. Patent Damages Hearings (May 2017 public comment version)

In late 2016, WG9 formed a drafting team to develop best practice recommendations for holding a damages-focused hearing relatively early in the case during which a number of damages issues can be addressed at one time rather than seriatim through separate motion practice at different stages of the case. This Section has now been published for public comment. To download, click [here](#).

This Section provides guidance to the bench and bar for:

- determining when an early damages hearing may or may not be appropriate
- determining the optimal timing for holding a damages hearing (i.e., the pros and cons of holding it at the summary judgment stage, the *Daubert* motion stage, or the motions *in limine* stage)
- the mechanics of a damages hearing, in particular procedures designed to require the earlier disclosure of and allow possibly for the earlier resolution of damages issues, without unfairly prejudicing either party.

C. WG9 Framework for Analysis of Standard-Essential Patent (SEP) and Fair, Reasonable, and Non-Discriminatory (FRAND) Licensing and Royalty Issues (Jan. 2023 Edition)

In 2015, WG9 formed a drafting team to address issues specific to alleged standard-essential patents (SEPs) and to consider the effects of commitments made to license patents on fair, reasonable, and non-discriminatory (FRAND) terms in infringement suits. The limited, and sometimes conflicting, case law that has been developed by judges struggling to address highly complicated areas of technology, economics, and the law in SEP/FRAND cases highlights the need in the patent community for this publication, which is designed to help practitioners and the judiciary identify and put into the appropriate context the types of issues that frequently arise in SEP/FRAND disputes.

Stage One of this *WG9 Framework for Analysis of Standard-Essential Patent (SEP) and Fair, Reasonable, and Non-Discriminatory (FRAND) Issues* was published for public comment in Feb. 2018. Stage Two of this publication addressed the remaining important SEP/FRAND issues identified by WG9 that were not addressed in Stage One, and was published for public comment in Nov. 2019. The final/post-public comment version of the entire *WG9 Framework* was published in Jan. 2023. To download, click [here](#).

Appendix A: WG10 Commentary on Patent Litigation Best Practices—Principles

The Principles that guided the development of the best practice recommendations in the *WG10 Case Management Issues from the Judicial Perspective Chapter* are:

Principle No. 1 – WG10 is developing these Best Practices to improve the system for resolving patent disputes and make it more fair and efficient. These Best Practices are to apply to and benefit all stakeholders in patent litigation, both bench and bar, and to and for all types of patent holders and accused infringers. These Best Practices should further the goals of Federal Rule of Civil Procedure 1 and “should be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding,” all to help ensure a non-frivolous patent litigation system.

Principle No. 2 – The parties should advise the court as soon as practicable, during case management conferences and on an ongoing basis, whether motions in this proceeding, or filings or petitions in parallel proceedings, are likely to be filed that may substantially affect the management of the case. The court’s case management schedule should require the filing of all such motions early enough to allow the parties a full and fair opportunity to address the matters raised and to facilitate a timely ruling by the court so that discovery, motion practice, and trial preparation can be streamlined.

Principle No. 3 – The parties should actively and cooperatively work to narrow the set of asserted claims, representative products, and prior art references in a good faith and efficient manner. [*see also* Discovery Principle No. 3]

Principle No. 4 – The parties should disclose, formally or informally, the basis for their positions and requests, to help the court and the parties understand the significance to the case of each and to mitigate against the presentation and litigation of issues that ultimately prove to be of little significance.

Principle No. 5 – Litigants should be encouraged to only file meritorious motions that will help resolve actual significant disputes in the litigation, and facilitate the expeditious presentation and resolution of such motions. The same concept should apply when oppositions to such motions are filed. Where litigants fail in this regard, whether initiated by motion or by the court *sua sponte*, the court should take appropriate action to remedy the party’s abuses, such as awarding fees or granting other relief.

Principle No. 6 – Lead counsel of both parties should directly manage their respective litigation strategies and procedures from the start of the case, and ensure

there is a close coordination between the issues the party is going to try and the preparations leading up to them.

The Principles that guided the development of the best practice recommendations in the *WG10 Pleading Standards Under Iqbal/Twombly Chapter* are:

Principle No. 1 – The pleadings should provide sufficient disclosures for the parties to have reasonable notice of what claims, products/processes, and defenses are in dispute, allowing the parties to focus and narrow the issues more efficiently. At the same time, the pleading requirements should not be so onerous that they result in unfair burdens and become the subject of significant motion practice (e.g., Rule 12 challenges) that bog down the litigation.

Principle No. 2 – A clear, uniform standard should be developed for pleading claims of patent infringement to (i) avoid disputes over the sufficiency of the pleadings, which consume significant resources of the parties and the courts, and (ii) avoid forum shopping.

The Principles that guided the development of the best practice recommendations in the *WG10 Mediation Chapter* are:

Principle No. 1 – Mediation is designed to benefit the parties to a patent dispute by providing an opportunity for a mutually acceptable resolution of their claims in whole or in part.

Principle No. 2 – When used in connection with pending patent litigation, mediation should be administered to promote the just, speedy, and cost-effective resolution of the case.

Principle No. 3 – Consistent with the first two principles, mediation of patent cases should promote the overall goals of the patent system and the judicial process.

The Principles that guided the development of the best practice recommendations in the *WG10 Parallel USPTO Proceedings Chapter* are:

Principle No. 1 – The PTAB, ITC, and district courts should take steps to harmonize parallel proceedings and exercise their discretion, when possible, to reduce abusive litigation and foster just, speedy, and inexpensive determinations.

Principle No. 2 – Parties to PTAB proceedings should be afforded a fair opportunity to present appropriate evidence and argument both before and after institution.

The Principles that guided the development of the best practice recommendations in the *WG10 Discovery Chapter* are:

Principle No. 1 – Discovery should be proportionate with the overall nature of the dispute, including factors such as the number of patents or patent families asserted, complexity of the technology involved, the number of accused products involved, the past damages or future value (either monetary or injunctive) of a specific patent litigation, and the importance of the discovery sought to the resolution of the issues.

Principle No. 2 – The parties should meet and confer before the first scheduling conference about: the substantive basis for their allegations; the specific identification of the claims being asserted and products alleged to infringe, damages theories, and known prior art; the scope of discovery needed by each party; and confidentiality issues. The parties should continue to meet and confer about the above throughout the case and, to the extent possible, to resolve any disputes expeditiously and independent of court intervention.

Principle No. 3 – Each party should be required to disclose primary relevant documents and contentions early in the discovery process and have an ongoing duty to disclose any additional such documents once it learns of their existence or relevancy; the court should consider not allowing untimely produced documents or contentions to be admitted at trial.

Principle No. 4 – Where appropriate and necessary, the court should seek to resolve discovery disputes expeditiously and should use some form of gating function to determine which disputes truly require formal motion practice.

Principle No. 5 – Discovery sanctions should not be routinely requested and should not be pursued by a party in a manner that overshadows the substantive issues in the case. Routinely seeking discovery sanctions, or conducting discovery in a manner primarily aimed at “catching” your opponent in a discovery error is not a proper function of the provisions providing for sanctions or an efficient use of client or judicial resources.

Principle No. 6 – If a party’s or attorney’s conduct during discovery warrants fee shifting or sanctions, the court should consider appropriate monetary or evidentiary sanctions against the party or counsel to remedy, deter, or punish such conduct.

The Principle that guided the development of the best practice recommendations in the *WG10 Summary Judgment Chapter* is:

Principle – Summary judgment motions should be filed solely for the purpose of eliminating trial or issues where there are no reasonably disputed facts, and never as a discovery tool or to “educate” the court. Decisions to file summary judgment motions should be directly managed by the lead counsel with these precepts in mind.

The Principles that guided the development of the best practice recommendations in the *WG10 Section 101 Motions on Patentable Subject Matter Chapter* are:

Principle No. 1 – The court should consider establishing procedures requiring the parties to notify the court whether they intend to assert a § 101 patent eligibility challenge and to assist the court in evaluating the most appropriate stage of the case to decide that challenge.

Principle No. 2 – The court should, where appropriate, decide motions involving § 101 patent eligibility challenges early in the litigation provided the court is able to render a decision based on sufficient evidence and adequate process.

The Principles that guided the development of the best practice recommendations in the *WG10 Use of Experts, Daubert, and Motions in Limine Chapter* are:

Principle No. 1 – An expert’s testimony should be fairly limited to the opinions and bases for those opinions disclosed in the expert’s Rule 26 report, and a party presenting expert testimony should seek permission to serve a supplemental report as soon as an evidentiary issue with a previously served expert report is identified. An expert should not be permitted to supplement a Rule 26 report through deposition or declaration beyond what was fairly set forth in the report.

Principle No. 2 – A court should exclude expert testimony that is not supported by the expert’s Rule 26 report. Strict adherence to the view that parties must “show their cards” as to their final legal positions during expert discovery will discourage “sandbagging” and result in a fairer process that minimizes surprises at trial.

The Principle that guided the development of the best practice recommendations in the *WG10 Streamlining Lower-Value Patent Cases Chapter* is:

Principle No. 1 – WG10 is developing Best Practices to improve the system for resolving patent disputes and make it more fair and efficient. These Best Practices apply to and benefit all stakeholders in patent litigation, both bench and bar, and to and for all types of patent holders and accused infringers. These Best Practices should further the goals of Federal Rule of Civil Procedure 1 and “should be construed and administered to secure the just, speedy, and inexpensive determining of every action and proceeding,” all to help ensure a fair and efficient patent litigation system.

The Principles that guided the development of the best practice recommendations in the *International Trade Commission Section 337 Investigations Chapter* are:

Principle No. 1 – With the expedited schedule utilized by the ITC, issues for trial should be identified as soon as possible and discovery should be limited to such issues.

Principle No. 2 – ITC discovery should be proportionate with the overall nature of the dispute. However, even in complex ITC patent investigations, the determination of proportionality also should take into account the limited time available and inherent difficulties in obtaining information from foreign non-party entities.

Principle No. 3 – Each party should be required to disclose primary relevant documents and contentions very early in the discovery process and have an ongoing duty to disclose any additional such documents once it learns of their existence or relevancy. While some degree of supplementation should be allowed if done in a timely manner, the ALJ should consider not allowing untimely produced documents or contentions to be admitted at trial absent good cause.

Principle No. 4 – To assist in the prompt disclosure of material issues in dispute, parties are encouraged to use contention interrogatories regarding lack of infringement, invalidity, and domestic industry and to provide substantial responses to contentions on the schedule established by the ALJ or as otherwise agreed by the parties.

Principle No. 5 – Where appropriate and necessary, the ALJ should try to resolve discovery disputes expeditiously and should use some form of gating function to determine which disputes truly require formal motion practice.

Principle No. 6 – Discovery sanctions should not be routinely requested and should not be pursued by a party in a manner that overshadows the substantive issues in the case.

Principle No. 7 – If a party's or attorney's conduct during discovery warrants fee-shifting or sanctions, the ALJ should consider appropriate monetary or evidentiary sanctions against the party or counsel to remedy, deter, or punish such conduct.

Principle No. 8 – If it is likely that the construction of disputed claim terms will be critical to or dispositive of any issues of infringement, invalidity, or the technical prong of domestic industry, a claim construction hearing should be held and a decision should be issued in advance of expert reports and contention responses where practicable.

The Principle that guided the development of the *Framework for Analysis of Venue Selection for Global Patent Litigation: Strategic Considerations* is:

Principle No. 1 – WG10 is developing Principles and Guidelines to permit litigants to identify the venues best suited for resolution of their global patent portfolio

disputes and to litigate them in a fairer and more efficient manner for the benefit of all stakeholders in patent litigation, including both bench and bar.

The Principle that guided the development of the *WG10 Framework for Analysis for the Efficient Resolution of Disputes before the Forthcoming European Unified Patent Court* is:

Principle No. 2 – The accurate and efficient resolution of EU-wide patent disputes before the UPC will be improved by crossfertilization of best practices developed in different jurisdictions attempting to solve the same problems, and the newly-formed UPC addressing these disputes will benefit from having a greater understanding of the different approaches taken across Europe.

The Principles that guided the development of the best practice recommendations in the *WG10 Commentary on Cross-Border Discovery in US Patent and Trade Secret Cases* are:

Principle No. 1 – Because of the complexities associated with cross-border discovery and the time sensitivity of certain case management deadlines in patent or trade secret litigation, the parties should engage with each other and the court at the earliest possible point in the litigation—preferably before the case management conference—about what cross-border discovery may be required, what impediments to that discovery may exist, and how they and the court can work together to facilitate the discovery. The parties should continually reassess the need for such discovery throughout the litigation so that issues can be promptly identified and efficiently resolved.

Principle No. 2 – In setting and enforcing expectations throughout the litigation for the scope, timing, and mechanisms for cross-border discovery, the court may balance the proportionality of such discovery under Federal Rule of Civil Procedure 26(b)(1) with case management concerns, including: the impact on case management deadlines; the existence of legal impediments to the discovery in the country where the discovery is located; the cost and logistical challenges of international travel; and the importance of the discovery to the issues in the case.

Principle No. 3 – For cross-border discovery issues, the parties should be prepared to address with the court considerations of comity, especially where blocking statutes or data privacy concerns are at issue. The comity analysis may emphasize certain factors, such as whether noncompliance with the request would undermine important intellectual property interests of the United States, and whether compliance with the request would undermine important interests of the state where the information is located.

## Appendix B: WG9 on Patent Damages and Remedies Commentaries—Principles

The Principles that guided the development of the best practice recommendations in the *WG9 Commentary on Patent Reasonable Royalty Determinations* are:

Principle No. 1 – The reasonable royalty in patent infringement matters should fairly compensate the patent holder for the use made by the infringer of the patented invention based on the evidence presented.

Principle No. 2 – Whether the royalty should be structured as a running royalty or a lump sum should be considered explicitly in the reasonable royalty analysis.

Principle No. 3 – In cases involving an accused product with many components, the royalty should not be applied to the entire market value of the accused product unless it is shown that the patented feature or method provides the basis for customer demand for the product or substantially creates the value of the component parts.

Principle No. 4(a) – Where a patent claim is drawn to an individual component of a multi-component product that is found to infringe, and the entire market value rule does not apply, it is necessary to apportion the royalty base between its patented and unpatented features.

Principle No. 4(b) – It may be appropriate to consider the smallest salable unit containing the feature or embodying the patented method for use as the apportioned royalty base; however, consideration of further apportionment may be required in assessing the royalty rate to ensure that the royalty reflects only the value of the patented features.

Principle No. 5 – Any proposed comparable license offered as “comparable” to the hypothetical license must be evaluated for its similarities to and differences from the hypothetical license.

Principle No. 6 – Where an accused product incorporates multiple technologies, once the proper royalty base has been determined, the royalty rate should reflect the relative contribution of the patented invention as compared to the other technologies incorporated into the royalty base.

Principle No. 7(a) – The reasonable royalty must reflect the extent to which the patented invention represents an improvement over any commercially acceptable and available noninfringing alternatives, including any such alternatives disclosed in the prior art. A royalty which over- or undervalues the inventive contribution of the patent claim is not reasonable.

Principle No. 7(b) – The total economic cost to the accused infringer of implementing the next best commercially acceptable and available noninfringing alternative may serve to cap the reasonable royalty award.

Principle No. 8 – The reasonable royalty normally should not encompass any value or premium attributable to market considerations unrelated to the benefits and advantages of the patented invention, such as any switching costs, lock-in costs, patent-holdup costs, or other similar costs.