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PATENT ARBITRATION: THE UNDERUTILIZED PROCESS FOR RESOLVING INTERNATIONAL
PATENT DISPUTES IN THE PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES

By
Alessandra Emini*

I. INTRODUCTION

“The theoretical advantages of arbitration over court adjudication are manifold. . . . These theoretical advantages [however] are not always fully realized.” – Frank Sander¹

International patent arbitration is an underutilized method of dispute resolution that has the potential to yield many benefits for companies within the pharmaceutical and biotechnology industries. These industries would benefit from international patent arbitration because patents are the companies’ primary assets, the costs of research and development (“R&D”) are high, and limited patent monopolies create a tight time constraint for receiving a return on costs. Additionally, the positive impact the biotechnology and pharmaceutical industries have on universal health puts pressure on the companies’ need for a quick, efficient, and low cost international resolution process. Arbitration provides just that. Arbitration is a blank canvas on which the parties have complete autonomy to modify the procedures to best fit their needs. This autonomy places a substantial amount of beneficial power in the hands of the companies and significantly diminishes the constraints of international litigation. The beneficial impact international arbitration has had for companies led it to become the standard method of dispute resolution among the energy, construction, insurance, shipping and commodities industries. Furthermore, this trend has extended to countries as a whole with many countries openly endorsing international arbitration. In particular, the United States Supreme Court has explicitly recognized “an emphatic federal policy in favor of arbitral dispute resolution.”² Once the biotechnology and pharmaceutical industries embrace the use of patent arbitration, they will experience benefits that simply cannot be achieved in litigation.

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¹ Peter L. Michaelson, *Patent Arbitration: It Still Makes Good Sense*, 7 LANDSLIDE (JOURNAL OF THE ABA SECTION OF INTELLECTUAL PROPERTY), (July 23, 2015), 1, 8, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2635036 (quoting *CI Arb Costs of International Arbitration Survey 2011*, CHARTERED INST. OF ARBITRATORS (CIARB), at ii (2011)).

² *Marmet Health Care Ctr., Inc. v. Brown*, 132 S. Ct. 1201, 1203 (2012).

A. Background

At their core, patents are the life-blood of the pharmaceutical and biotechnology industries.³ Patents create property rights in the physical and intangible inventions of artistic persons.⁴ A patent, however, does not provide an international right of ownership of the invention to the patentee.⁵ A patent is only enforced within the jurisdictions in which the patentee applied for the patent and within the sovereign states that granted it.⁶ For an invention to be patentable, it must be a “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”⁷ The global-standard life of a patent is twenty years from the date of filing.⁸ Once granted, the patent holder has the exclusive right to choose who “makes, uses, offers to sell, or sells” the patented invention.⁹ However, the way in which a patent holder exercises this exclusive right varies by the industry.¹⁰ Some industries, such as the electronic industry, require a method of patent sharing and cross licensing because many new products contain previously patented technologies.¹¹ Alternatively, industries such as the pharmaceutical and biotechnology sectors use patents as equivalents to market products.¹² By equating patents to market products, these industries have to invest large sums of money in research, development, and clinical testing before placing their patented products into the marketplace.¹³ The high cost of R&D,¹⁴ the ease of reverse engineering pharmaceutical and biotechnology

³ Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT. J. TECH. MGMT., 98 (2000); see also Esteban Burrone, *Patents at the Core: the Biotech Business*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, http://www.wipo.int/sme/en/documents/patents_biotech_fulltext.html.

⁴ Bruce Lehman, *The Pharmaceutical Industry and the Patent System*, INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE, 1 (2003).

⁵ *Id.* at 4.

⁶ *Id.*

⁷ 35 U.S.C. § 101 (2012).

⁸ Lehman, *supra* note 4, at 4.

⁹ 35 U.S.C. § 271(a) (2012).

¹⁰ Lehman, *supra* note 4, at 2.

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

products,¹⁵ and the impact these products have on universal health¹⁶ highlight the indispensable need for and significant role of patents in the pharmaceutical and biotechnology industries.

The pharmaceutical and biotechnology industries rank among the top industries requiring patents to procure returns on R&D of new inventions and future products.¹⁷ In the biotechnology industry alone, patents granted by the United States Patent and Trademark Office increased 15% per year and those granted at the European Patent Office increased 10.5% per year from 1990-2000.¹⁸ These percentages are a stark contrast to the mere 5% annual increase in patents granted overall.¹⁹ The percentages reflect the fact that these industries rely heavily on intellectual property (“IP”) and invest nearly half of all revenues in R&D.²⁰ To illustrate, development and market approval can last longer than a decade and cost approximately \$2.6 billion on average.²¹ This cost rises to approximately \$2.9 billion in post-approval R&D.²² However, the return on the cost for R&D is reduced because nearly half of the patent term has passed before the drug or technology enters the market. This effectively cuts the patent life from 20 years to an average of 11.5 years.²³ The shortened exclusivity period is unique to these industries because unlike the computer and software industries, which can keep new inventions secret until their entrance into the market, medical research is highly regulated and scientists are obligated to share findings for the benefit of their peers.²⁴

Alongside the repayment of R&D, the imitation of new inventions is an area of large concern for these industries.²⁵ According to the founders of Nordic Biotech, “the present reality in drug development . . . is that almost any technology or compound can

¹⁵ Burrone, *supra* note 3.

¹⁶ 2015 *Biopharmaceutical Research Industry Profile*, PHARMACEUTICAL RES. AND MFR. OF AM., Apr. 2015.

¹⁷ Grabowski & Vernon, *supra* note 3, at 98 (referencing the study by R.D. Levin et al., *Appropriating The Returns from Industrial Research and Development*, BROOKINGS PAPERS ON ECON. ACTIVITY, 783 (1987)).

¹⁸ Org. for Econ. Co-Operation and Dev., GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES, 1, 8 (2002), <https://www.oecd.org/sti/sci-tech/2491084.pdf>.

¹⁹ *Id.*

²⁰ Burrone, *supra* note 3.

²¹ Joseph A. DiMasi, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, TUFT CENTER FOR THE STUDY OF DRUG DEVELOPMENT (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study (note that these figures are expressed in 2013 dollars).

²² *Id.*

²³ Harsha Rohatgi, *The Importance of Patents in the Pharmaceutical Industry*, EYESPAT (Feb. 2014), <http://www.eyespat.com/the-importance-of-patents-in-pharmaceutical-industry/>.

²⁴ Lehman, *supra* note 4, at 7.

²⁵ *Id.*

rapidly be reverse engineered.”²⁶ The products themselves often do not require “expensive and complex manufacturing infrastructures” and can therefore “be easily and cheaply replicated by copiers with little capital investment.”²⁷ The majority of capital investment is disproportionately placed into R&D and not into manufacturing. Thus, the exclusivity procured through patents is the only way for companies within these industries “to protect and receive a return” on their investments.²⁸ Furthermore, only 12% of all drugs that enter clinical trials are approved.²⁹ The low rate of marketplace success illustrates the necessity of patent protection for those drugs that are eventually released to the public. Without the incentive of patents to provide return on investments and prevent competitor product duplication, these industries would not create the life-saving products they are delivering today.³⁰

The impact the pharmaceutical and biotechnology industries have had on universal health is monumental. Since the peak of cancer death rates in the 1990s, there has been a decline of nearly 22%, with 83% of survival gains owed to new treatments and medicines.³¹ Since 1995 and the introduction of highly active antiretroviral treatment (HAART), the HIV/AIDS death rate has decreased by nearly 85% and approximately 862,000 premature deaths were averted in the United States alone.³² In 2014, for example, two drugs were approved to treat advanced melanoma, two antiviral combination therapies were approved to treat hepatitis C with “a cure rate of more than 90% in as few as eight weeks”, and four new antibiotics were approved to treat serious infections.³³ Therefore, because of the positive impact these industries have on universal health, the high costs of R&D, and the tight time constraint of their limited monopoly provided by patents,³⁴ pharmaceutical and biotechnology companies need to resolve patent disputes quickly, efficiently and at a low cost. This form of resolution can be achieved through international arbitration.

²⁶ Florian Schonharting & Christian Hansen, *Intellectual Property and Investment in Biotech*, in MEDICON VALLEY PATENT GUIDE, 1, 24 (2002), http://www.cbs.dtu.dk/courses/27614/material/patents/Medicon_Valley_Patent_Guide.pdf.

²⁷ Lehman, *supra* note 4, at 7.

²⁸ *Id.*

²⁹ Profile, *supra* note 16, at 2.

³⁰ *Id.* at 8.

³¹ *Id.* at 2.

³² *Id.*

³³ *Id.* at 11-12.

³⁴ Ronald E. Dimock & Michael Rubinger, *7 Benefits of Arbitration In A Patent Dispute*, LAW360 (Aug. 27, 2015), <https://www.law360.com/articles/695649/7-benefits-of-arbitration-in-a-patent-dispute>.

Historically, companies facing patent disputes have lagged behind in utilizing international arbitration as a tool for dispute resolution.³⁵ International arbitration has become a primary mechanism for companies resolving commercial disputes.³⁶ According to the PwC 2013 International Arbitration Survey, 52% of corporate respondents chose arbitration as their most preferred dispute resolution tactic, followed by court litigation with 28% of the vote.³⁷ By industry, 56% of respondents in the Energy sector and 68% of respondents in the Construction sector preferred arbitration to other methods of resolution.³⁸ This trend has also conveyed itself in countries as a whole with the United States being at the forefront of alternative dispute resolution having recognized “an emphatic federal policy in favor of arbitral dispute resolution.”³⁹ However, despite this trend, international patent disputes are rarely submitted to arbitration and are usually settled via litigation where jurisdiction is limited and the enforcement of awards is not guaranteed internationally.⁴⁰ This runs contrary to the increasing global impact of patents and the international push towards a unified patent system.⁴¹ When applied appropriately, the use of patent arbitration for companies in the pharmaceutical and biotechnology industries not only helps resolve international disputes in a nearly unified method, but it also provides confidentiality while saving significant time and costs.⁴²

II. THE INEFFICIENCIES OF LITIGATION

Patents are among the most important assets companies have within the pharmaceutical and biotechnology industries.⁴³ Patent protection is essential for these companies to ensure they remain competitive in the market and license their inventions to

³⁵ Felicia J. Boyd, *A Way To Efficiently Resolve International Patent Disputes*, LAW360 (Feb. 8, 2016), <https://www.law360.com/articles/743379/a-way-to-efficiently-resolve-international-patent-disputes>.

³⁶ *Id.*; see also *Forward: Guide to International Arbitration*, LATHAM & WATKINS, 1 (2015), <https://www.lw.com/thoughtleadership/guide-to-international-arbitration-2014> (“In modern times, arbitration became the standard method for resolving disputes in certain industry sectors (such as construction, commodities, shipping and insurance) where the arbitrators’ technical expertise was particularly valued.”).

³⁷ *Corporate Choices in International Arbitration*, PWC, 1, 6 (2013), <https://www.pwc.com/gx/en/arbitration-dispute-resolution/assets/pwc-international-arbitration-study.pdf>.

³⁸ *Id.* at 7.

³⁹ *Marmet*, 132 S. Ct. at 1203.

⁴⁰ Boyd, *supra* note 35.

⁴¹ See Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231.

⁴² Michaelson, *supra* note 1, at 3.

⁴³ David A. Allgeyer, *In Search of Lower Cost Resolution: Using Arbitration to Resolve Patent Disputes*, 12 CONFLICT MGMT. NEWSL. OF THE SEC. OF LITIG.’S COMMITTEE ON ALTERNATIVE DISP. RESOL. 1, 9 (2007).

others.⁴⁴ However, the value of patents places companies within these industries at a significant risk of entering litigation over patent disputes.⁴⁵ Between 2010 and 2012, in the top ten countries for patent suits – China, the U.S., Germany, France, Italy, Japan, India, Taiwan, England, and Canada – there were approximately 70,400 cases.⁴⁶ In the U.S., patent suits increased 120% since 2004.⁴⁷ Likewise, China had 9,680 suits filed in 2012, nearly 80% greater than the total number of suits filed in the U.S. that same year.⁴⁸ Yet, despite the trend of increasing patent litigation world-wide, the benefits of the litigation system are greatly outweighed by its inefficiencies.⁴⁹ This includes the length of time required to litigate a patent dispute, the high costs of discovery and motions, the unspecialized court systems that often include judges without technical backgrounds, and the public forum.

A. Extensive Length of Time to Litigate a Patent Dispute

The length of time to litigate a patent dispute is one of litigation's principal drawbacks. Parties of a patent dispute may only litigate the issue within a court and country that has jurisdiction.⁵⁰ To illustrate, in the U.S., time-to-trial averages two and a half years,⁵¹ and litigation can continue for as long as twenty-five years.⁵² For example, the longest lasting patent infringement case, *Hughes Aircraft Co. v. United States*, was filed in 1973 and remained unresolved until 1998, twenty-five years later.⁵³ Notably, time-to-trial has increased dramatically in the last twenty years in proportion to the rise of patent cases filed annually.⁵⁴ Once the parties have waited for litigation to commence, additional time

⁴⁴ Allgeyer, *supra* note 43, at 9.

⁴⁵ *Id.*; See also CRISPR UPDATE, <http://www.crisprupdate.com/category/crispr-patents/> (offering a present day example of a hard fought litigation patent dispute across two continents over the Crispr/Cas9 invention).

⁴⁶ *Significant Trends in Global Patent Litigation*, GLOBAL IP PROJECT, LLC, 2 (2015), <http://globalpatentmetrics.com/wp-content/uploads/2015/01/Significant-Trends-Slides-25-Jan-2015.pdf>.

⁴⁷ *Id.* at 10.

⁴⁸ Brian Love, Christine Helmers, and Markus Eberhardt, *Patent Litigation in China: Protecting Rights or the Local Economy?* (2016), <http://digitalcommons.law.scu.edu/facpubs/918>.

⁴⁹ Michaelson, *supra* note 1, at 3

⁵⁰ Lehman, *supra* note 4, at 4

⁵¹ Chris Barry et al., *Are We At An Inflection Point?*, 2016 PATENT LITIGATION STUDY (May 2016), <https://www.pwc.com/us/en/forensic-services/publications/assets/2016-pwc-patent-litigation-study.pdf>.

⁵² See e.g. *Hughes Aircraft Co. v. United States*, 140 F.3d. 1470 (Fed. Cir. 1998).

⁵³ *Id.*

⁵⁴ Barry, *supra* note 51, at 3.

is spent following the country's expansive rules of procedure.⁵⁵ These rules include exhaustive discovery, depositions, and potentially futile motions⁵⁶ resulting in patent litigation that averages 23.4 months.⁵⁷ The time to complete a patent suit is potentially lengthened by a "Markman" hearing as well.⁵⁸ Markman hearings, also referred to as "claim construction hearings," are pre-litigation hearings "in which a judge determines the meaning of words from the patent claims that are in dispute in a patent infringement lawsuit."⁵⁹ Even after the final decision is rendered in litigation, parties can appeal the court's result. In 2015, 80% of the decisions made on patent disputes in U.S. District Courts were appealed.⁶⁰ On average, an appeal adds an extra 30.8 months to the litigation process.⁶¹ Of those disputes appealed, 53% resulted in some type of a modification of the lower court ruling.⁶² Therefore, the average patent litigation in the U.S., from filing a claim to a decision rendered after an appeal, can last more than half a decade.

The U.S. is not the only country that has a lengthy patent litigation system. Courts in France, where approximately 350 patent cases are filed annually, take an average of 15 to 24 months to render a decision in the tribunal de grande instance.⁶³ If the decision is appealed, the cour d'appel takes an average of 24 months to render a judgment and, if the decision is brought to the Cour de cassation, the parties wait an additional 18 to 24 months for that court to render a final decision.⁶⁴ Courts in Korea faced with a first instance infringement lawsuit can take as little as 9 to 18 months to render a decision.⁶⁵ From filing to rendering a decision, however, an expedited review of a civil court invalidation action with a parallel infringement action lasts 2.5 to 4 years in civil court and 2 to 3.5 years in

⁵⁵ Michaelson, *supra* note 1, at 3.

⁵⁶ *Id.* at 5.

⁵⁷ Dimock, *supra* note 34.

⁵⁸ Allgeyer, *supra* note 43, at 9.

⁵⁹ MARKMAN HEARING, <http://www.markmanhearing.org>.

⁶⁰ Barry, *supra* note 51, at 2.

⁶¹ Dimock, *supra* note 34.

⁶² Barry, *supra* note 51, at 2.

⁶³ Global IP Project, *supra* note 46, at 23. The tribunal de grande instance is the court which hears first instance disputes which would not otherwise be attributed to a different court and play a similar role to the District Courts in the United States.

⁶⁴ *Id.* The cour d'appel is the appeals court that reviews decisions rendered in the tribunal de grande instance. The Cour de cassation is the court of last resort and is similar to that of the Supreme Court in the United States.

⁶⁵ *Id.* at 36.

KIPO, Korea's IP tribunal.⁶⁶ In spite of each country's average patent litigation time, national courts in international litigation have delays that can easily exceed five to ten years.⁶⁷ Ultimately, the patent litigation system results in a significant amount of lost time, with IP remaining in patent legal limbo until the dispute is resolved.⁶⁸

B. The High Costs of Litigating an International Patent Dispute

The costs to litigate a patent dispute are increased by exhaustive discovery, the necessity of witness testimony, pretrial depositions, and disputes regarding the discovery process.⁶⁹ A 2015 study conducted by the American Intellectual Property Law Association ("AIPLA") found that the average cost for litigation in a U.S. patent infringement case for a claim over \$25 million was \$6.3 million, with the costs of discovery averaging about \$3.7 million.⁷⁰ Alongside the U.S., the United Kingdom is also considered a high-cost country for patent litigation.⁷¹ For example, Research in Motion spent £6 million (\$9.1 million) in its litigation case against Visto and Johnson & Johnson spent £3.7 million (\$5.7 million) in its contact lens case against CIBA.⁷² International enforcement of patents, however, typically involves multiple parallel judicial proceedings of similar patent claims in various national courts.⁷³ Thus, companies are forced to enforce their patents before multiple courts across several continents and within a multitude of different countries. The European Commission issued a February 2009 report that estimated party costs for large commercial cases in France, Germany, the Netherlands, and the U.K.⁷⁴ These costs amount to €200,000 (\$266,000) in France and the Netherlands, €250,000 (\$332,000) in Germany, and €1.5 million (\$2 million) in the U.K.⁷⁵ The excessive costs of patent litigation leave

⁶⁶ Global IP Project, *supra* note 46, at 39.

⁶⁷ Michaelson, *supra* note 1, at 6.

⁶⁸ Allgeyer, *supra* note 43, at 9.

⁶⁹ *Id.*

⁷⁰ *AIPLA 2015 Report of the Economic Survey*, INTELL. PROP. INS. CORP. (2015), <http://www.patentinsuranceonline.com/wp-content/uploads/2016/02/AIPLA-2015-Report-of-the-Economic-Survey.pdf> (compiling the average costs of litigation found within the *2015 Report of the Economic Survey* released by the American Intellectual Property Law Association).

⁷¹ World Intell. Prop. Org. (WIPO), *IP Litigation Costs*, WIPO MAGAZINE, Feb. 2010, at 1, 6, http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2010/wipo_pub_121_2010_01.pdf.

⁷² *Id.* at 8 (using the 2010 conversion rate between the pound and the U.S. dollar used to express equivalency).

⁷³ *Id.* at 12.

⁷⁴ *Id.*

⁷⁵ *Id.* (using the 2009 conversion rate between the euro and the U.S. dollar used to express equivalency).

small and medium-sized enterprises unable to enforce their international patent rights⁷⁶ and many alleged infringers settle to avoid legal expenses even if they were likely to succeed in their defense in court.⁷⁷

C. Court Systems and Judicial Knowledge on the Subject Matter

Internationally, each country's patent litigation system and requirements for specialized judges with technical backgrounds are different.⁷⁸ Studies suggest that specialized patent courts with technically trained judges have a lower patent claim reversal rate.⁷⁹ Donna M. Gitter conducted a study comparing the reversal rate of U.K. specialist patent judges, all with technical experience, to the reversal rate of U.S. District Court judges.⁸⁰ Gitter concluded that the reversal rate of U.S. District Courts outnumbered that of the specialized U.K. patent courts, suggesting that specialized patent courts have a lower reversal rate.⁸¹ This is a strong indicator that judicial knowledge on the subject matter saves time and costs.

Of the top ten countries in patent litigation, only two countries – Taiwan and the U.K. – have specialized IP courts, and Canada is the only country with a trial court that hears only IP cases.⁸² However, five countries – China, Japan, France, Germany, and Italy – have a specialized IP division in their court systems.⁸³ Yet the U.S., the country with the second largest number of patent cases heard, and India, the seventh leading country in patent disputes, have no specialized IP court system at all.⁸⁴ The international

⁷⁶ WIPO, *supra* note 71, at 12.

⁷⁷ Michaelson, *supra* note 1, at 1.

⁷⁸ Rohazar Wati Zuallcoble et al., *Study on Specialized Intellectual Property Courts*, THE INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE AND THE UNITED STATES PATENT AND TRADEMARK OFFICE, 1, 11-13 (2012).

⁷⁹ Donna M. Gitter, *Should the United States Designate Specialist Patent Trial Judges? An Empirical Analysis of H.R. 628 in Light of the English Experience and the Work of Professor Moore*, 10 COLUM. SCI. & TECH. L. REV. 169, 193 (2009); *see also*, Ryan S. Goldstein et al., *Specialized IP Trial Courts Around the World*, INTELL. PROP. & TECH. L.J., 1, 3 (2006) (“[E]nforcement of IP rights can often be problematic because trial judges and laypeople on juries generally do not have the necessary IP law training or technical backgrounds to properly apply IP standards with uniformity.”).

⁸⁰ Gitter, *supra* note 79, at 193.

⁸¹ *Id.* at 195.

⁸² Zuallcoble, *supra* note 78, at 11-13.

⁸³ *Id.*

⁸⁴ *Id.*

inconsistency of specialized courts and judges with technical backgrounds can leave parties with varying international decisions on the efficacy and validity of their patents.

D. Use of a Public Forum in Litigation

A public forum, which is present in most court systems, has its benefits. These benefits include a public result that can serve as a preventive measure against other competitors in future litigation disputes.⁸⁵ Courts generally respect that the public has a right to access information on litigation materials and testimony; therefore, courts are less likely to allow for a blanket confidentiality designation on such matters.⁸⁶ However, confidentiality might be a necessity for a party in a patent suit because sensitive technical information is frequently shared in court.⁸⁷ In particular, given the ease of reverse engineering inventions in the pharmaceutical and biotechnology industries,⁸⁸ confidentiality is crucial in protecting the IP rights of companies in these industries.

III. ARBITRATION AS AN ALTERNATIVE

As opposed to litigation, arbitration offers a dispute resolution process that reduces time, costs and public knowledge while providing an informed and binding decision on the merits. Arbitration is a contractual agreement between parties that mutually agree to bring disputes before an arbitrator.⁸⁹ This agreement can be made during the negotiations of a business contract or after a dispute has arisen.⁹⁰ In a written document, the arbitration agreement is written in an arbitral clause. The arbitral clause serves as a roadmap to the arbitration.⁹¹ Arbitral clauses may include the number of arbitrators on the panel, the scope of arbitration, what laws will govern, which institutional rules are applicable, where the

⁸⁵ Michaelson, *supra* note 1, at 2-3.

⁸⁶ *Id.*

⁸⁷ Dimock, *supra* note 34.

⁸⁸ Schonharting, *supra* note 26, at 24.

⁸⁹ Boyd, *supra* note 35.

⁹⁰ *Id.*

⁹¹ *Id.*

arbitration will be held, and any other important components the parties find necessary to admit.⁹² In other words, arbitration can be tailored to the parties' needs.⁹³

Arbitration has been increasingly utilized as a dispute resolution process across industries in recent years. This is exemplified by the number of disputes submitted to arbitration across ten institutions⁹⁴ which shows that the caseload among these institutions has increased by approximately 458% between 1993 and 2011.⁹⁵ To date, the World Intellectual Property Organization ("WIPO") has managed approximately 450 mediation, arbitration, and expert determination cases.⁹⁶ The majority "of these cases have been filed in recent years."⁹⁷ Additionally, as of June 2015, 35% of all WIPO Mediation and Arbitration cases involve patents.⁹⁸ This trend demonstrates that arbitration is a preferred substitute to litigation in many cases.

Arbitration provides a viable alternative to litigation and indispensable benefits when utilized correctly. International arbitration is more efficient and less costly than its litigation counterpart.⁹⁹ Most international patent suits involve the risk of parallel litigation proceedings in multiple national courts, which can result in high costs and conflicting court rulings.¹⁰⁰ International arbitration can eliminate this risk by resolving multijurisdictional disputes in a single proceeding.¹⁰¹ Unlike litigation where jurisdiction is dependent upon the parties' residential status, arbitration allows for the choice of procedural and substantive

⁹² Boyd, *supra* note 35; *see also*, GARY BORN, INTERNATIONAL ARBITRATION CASES AND MATERIALS 46 (2d ed. 2015) ("Most modern arbitration legislation affirms the parties' autonomy to agree upon arbitral procedures...").

⁹³ Michaelson, *supra* note 1, at 3. (providing that arbitration is "a blank canvas on which parties can collectively create the exact process they need and no more.").

⁹⁴ The ten institutions reviewed for their caseload between 1993 and 2011 are the American Arbitration Association, British Columbia International Commercial Arbitration Centre, China International Economic and Trade Arbitration Commission, Honk Kong International Arbitration Center, International Chamber of Commerce, The Japan Commercial Arbitration Association, Korean Commercial Arbitration Board, The Kuala Lumpur Regional Centre for Arbitration, The London Court of International Arbitration, London Maritime Arbitrators Association, The Arbitration Institute of Stockholm Chamber of Commerce, and Singapore International Arbitration Centre.

⁹⁵ Born, *supra* note 92, at 46.

⁹⁶ *WIPO Caseload Summary*, WIPO, <http://www.wipo.int/amc/en/center/caseload.html>.

⁹⁷ *Id.*

⁹⁸ Joyce A. Tan, *WIPO Guide on Alternative Dispute Resolution Options for Intellectual Property Offices and Courts*, WIPO ARB. AND MEDIATION CTR., 1, 20 (2015), http://www.kipo.go.kr/upload/en/download/ADR_Guide.pdf.

⁹⁹ Dimock, *supra* note 34.

¹⁰⁰ Michaelson, *supra* note 1, at 7.

¹⁰¹ *Id.*

laws and the place of arbitration regardless of where the parties reside.¹⁰² While litigation is a one-size-fits-all model,¹⁰³ arbitration is flexible and offers the opportunity for a quicker resolution of the dispute, lower financial burden on the parties, arbitrators who are specialized in the technical field at issue, confidentiality of the proceeding, avoidance of a jury, and international enforceability of the decision rendered.

A. Arbitration Takes Less Time to Complete Than Its Litigation Counterpart

Arbitration is praised for providing a prompt resolution than litigation.¹⁰⁴ In recent years, corporations have expressed concern over delays in international arbitral proceedings.¹⁰⁵ Despite these concerns, a survey conducted by WIPO found that, on average, international arbitration proceedings take only 40% of the time required to complete an international litigation proceeding.¹⁰⁶ The average arbitral proceeding lasts for approximately seven months.¹⁰⁷ This quick resolution is accomplished in a number of ways, including subjecting the arbitrator's pay to a potential reduction when rendering a decision that takes longer than the time agreed upon by both parties or through institutional rules which instill time limits on how long a tribunal can take to render an award.¹⁰⁸ In the absence of institutional provisions or when parties choose to participate in *ad hoc* arbitration, parties can contractually agree to limit the time each party has to present its case before the tribunal in order to expedite the process.¹⁰⁹ Parties may also choose to undergo expedited arbitration, which limits procedures and discovery in order to reach a more immediate resolution.¹¹⁰

Litigation also offers parties the opportunity to appeal the decisions rendered in the court below. This adds a significant amount of time to the proceedings. However, the decision rendered by the arbitral tribunal is final and binding on the parties neither can

¹⁰² Boyd, *supra* note 35.

¹⁰³ See Michaelson, *supra* note 1, at 3 (“Arbitration does not follow a one-size-fits-all litigation template...”).

¹⁰⁴ Boyd, *supra* note 35.

¹⁰⁵ PwC, *supra* note 37.

¹⁰⁶ WIPO, *Results of the WIPO Arbitration and Mediation Center International Survey on Dispute Resolution in Technology Transactions*, Arbitration and Mediation Center (Mar. 2013), 31-32 (surveying a total of 393 respondents in 62 countries, with 12% of respondents within the pharmaceutical and biotechnology industries).

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ Michaelson, *supra* note 1, at 5.

¹¹⁰ Dimock, *supra* note 34.

appeal the holding.¹¹¹ That is not to say that arbitration receives no judicial appellate review, but it is only under limited circumstances.¹¹² Notably, arbitral institutions have begun including an arbitral appellate procedure to which the parties can contractually agree.¹¹³ Arbitral award appeals are conducted by a separate arbitral panel in a second tribunal.¹¹⁴ Overall, arbitration provides various alternatives for parties in order to resolve their disputes rapidly and prevent patent legal limbo.

B. The Cost of Arbitration Is Less Than Litigation

Another attribute for which arbitration is highly praised is cost savings. According to a survey on dispute resolution conducted by WIPO, arbitration saves, on average, 55% in costs compared to litigation.¹¹⁵ The highest cost driver in litigation is discovery; however, discovery in arbitration is limited and the rules are simple.¹¹⁶ The rules of evidence do not need to conform to the legal rules of the country whose law governs the contract, thus making the process less extensive and arduous.¹¹⁷ The arbitrator determines the necessity and validity of evidence and the parties can contractually agree to what extent discovery may extend.¹¹⁸ In other words, discovery may be as broad or as narrow as the parties desire. The International Institute for Conflict Prevention and Resolution provides

¹¹¹ Dimock, *supra* note 34.

¹¹² Michaelson, *supra* note 1, at 5.

¹¹³ *Id.* Arbitral appellate proceedings are under scrutiny for judicializing the arbitration process. However, even with an appeals process, arbitration still maintains the benefits of specialized arbitrators, confidentiality, avoidance of a jury and enforceability that its litigation counterpart does not. *See also* Bayer CropScience AG v. Dow AgroSciences LLC, C.A. No. 2-00047, 2012 WL 287485 (E.D. Va. July 13, 2012). The arbitral tribunal awarded Bayer \$455 million and a post-award interest rate of 8%. This award is egregious as it fails to conform to binding legal precedent and U.S. Patent Policy; however, due to the District Court's limited ability to review arbitral awards, the award was confirmed. This case is currently on appeal before the 4th Circuit Court of Appeals. Dow AgroSciences LLC would have benefited from an arbitral appellate proceeding where parties agreed upon a time constraint for the tribunal and permitted them to review the merits of the case.

¹¹⁴ *Id.*

¹¹⁵ WIPO, *supra* note 105.

¹¹⁶ Michaelson, *supra* note 1, at 4.

¹¹⁷ *Id.*; *see also*, Rule R-34(a) of the 2013 American Arbitration Association (AAA) Commercial Arbitration Rules (stating that the "conformity to legal rules of evidence shall not be necessary.").

¹¹⁸ *Id.*

a protocol of levels with increasing amounts of physical and electronic discovery.¹¹⁹ In using this protocol, parties can agree which level to follow during arbitration to determine the level of discovery.¹²⁰

Aside from discovery, other cost drivers in litigation are futile motions, the use of experts,¹²¹ and jury trials.¹²² Futile motions can be readily avoided in arbitration because arbitrators have discretion in choosing whether or not to accept a motion.¹²³ Furthermore, parties can limit the necessity for experts by selecting an arbitrator with a technical background and expertise in the field.¹²⁴ Lastly, parties save costs by bypassing a jury trial. Oftentimes, jury trials require parties to conduct mock trials beforehand, which is costly.¹²⁵ Ultimately, arbitration provides efficient cost-saving modalities to patent disputes.

C. Arbitrators Chosen by the Parties Can Be Specialized in the Required Technical Field

In the judicial process, parties cannot choose their judges. However, in arbitration parties may choose their arbitrators.¹²⁶ The arbitral tribunal generally consists of either one or three arbitrators.¹²⁷ The parties get to choose their arbitrators based on their needs for the dispute at hand.¹²⁸ Since patent disputes in the pharmaceutical and biotechnology industries often involve complex scientific and technological issues, the parties can choose at least one arbitrator with expertise in the field in an effort to reach a quick and cost-effective resolution.¹²⁹ For example, an arbitral tribunal can consist of an arbitrator with

¹¹⁹ *Protocol on Disclosure Documents and Presentation of Witnesses in Commercial Arbitration*, INT'L INST. FOR CONFLICT PREVENTION & RESOLUTION (2009) , <https://www.cpradr.org/resource-center/protocols-guidelines/protocol-on-disclosure-of-documents-presentation-of-witnesses-in-commercial-arbitration>.

¹²⁰ *Id.*

¹²¹ Michaelson, *supra* note 1, at 5.

¹²² Dimock, *supra* note 34.

¹²³ Michaelson, *supra* note 1, at 5; *see also* Rule R-32(b) of the 2013 AAA Commercial Arbitration Rules (“The arbitrator, exercising his or her discretion, shall conduct the proceedings with a view to expediting the resolution of the dispute...”).

¹²⁴ Boyd, *supra* note 35.

¹²⁵ Dimock, *supra* note 34.

¹²⁶ Boyd, *supra* note 35.

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*; *see also* Dimock, *supra* note 34.

extensive legal knowledge to assess the legal issues at hand, another arbitrator with a strong technical background, eliminating the need to simplify the case, and a third arbitrator with financial knowledge to determine the appropriate awards.¹³⁰ Resolving the dispute before a tribunal with varying technical expertise provides the fairest opportunity for the parties to resolve a patent dispute quickly and cost-effectively.¹³¹

D. Arbitral Proceedings Can Be Private and Confidential

Unlike litigation, which is always conducted in a public forum, arbitration is private unless the parties agree otherwise.¹³² Arbitrators are inherently sworn to secrecy about the proceedings of an arbitration, while parties are not.¹³³ Even though parties are not per se sworn to secrecy, they may contractually agree to a confidentiality provision in their arbitral clause or agree to one post dispute.¹³⁴ The privacy of arbitral proceedings is particularly important in patent disputes, which oftentimes involve sensitive technical information.¹³⁵ Another benefit of a confidentiality provision is that privacy allows the disputes to be resolved without attention from media and competitors.¹³⁶ A byproduct is the increased likelihood of preserving the commercial relationship between the parties.¹³⁷ Such a relationship is less strained in a private setting where the interactions can be informal and where outside commentary and ridicule are eliminated.¹³⁸ Furthermore, commercial relationships with third-party companies are not impacted by exposing sensitive financial information, terms and conditions, royalty rates, and more.¹³⁹

¹³⁰ Dimock, *supra* note 34; *see also* Boyd, *supra* note 35; Allgeyer, *supra* note 43, at 10.

¹³¹ Dimock, *supra* note 34.

¹³² *Id.*

¹³³ Allgeyer, *supra* note 43, at 10.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ Dimock, *supra* note 34.

¹³⁸ *Id.*

¹³⁹ *Id.*

E. Arbitration Does Not Require a Jury

In the past five years, juries have decided 75% of the damage awards in patent litigation in the U.S.¹⁴⁰ Median awards decided by juries have been sixteen times greater than median bench trial awards.¹⁴¹ This discrepancy occurs because jury members are not required to have any specific technical expertise.¹⁴² Their lack of knowledge on the subject matter obligates parties to obtain experts in the field in order to simplify the patent or issue.¹⁴³ Oversimplification runs the risk that juries fail to fully appreciate the details of the patent dispute, potentially leading to improper and unreasonable decisions.¹⁴⁴ Additionally, jury members are traditionally swayed by factors other than providing justice.¹⁴⁵ For example, jury members may have a personal bias or empathy for the party whom they view as the “little guy.”¹⁴⁶ Lastly, juries are not required to explain their decisions.¹⁴⁷ Alternatively, parties in an arbitration may contractually agree that the arbitral award include a document explaining the tribunal’s reasoning for rendering such an award.¹⁴⁸ Therefore, arbitration can help reduce bias, prevent oversimplification, and provide for a logical and well-reasoned award.¹⁴⁹

F. Arbitral Rulings Have a Greater Chance of International Enforceability

International arbitration awards are enforceable in most countries around the world.¹⁵⁰ The international treaty known as the New York Convention,¹⁵¹ ratified in 1959,

¹⁴⁰ Barry, *supra* note 51, at 2 (noting that this percentage does not include Abbreviated New Drug Application-related litigation).

¹⁴¹ *Id.* at 1.

¹⁴² Dimock, *supra* note 34.

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ Dimock, *supra* note 34.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ Boyd, *supra* note 35.

¹⁵¹ New York Convention, June 10, 1958, 21 U.S.T. 2517, 330 U.N.T.S. 38.

has been adopted by 156 member states.¹⁵² The Convention requires that all member states enforce arbitration agreements between parties and recognize arbitral awards that were decided in other member states.¹⁵³ Even though the New York Convention creates a global arbitral award enforcement system, however, not all countries recognize arbitral awards on patent validity and infringement disputes.¹⁵⁴ In other words, even if two parties contractually agree to arbitrate such disputes, enforcement of the award will not be recognized in those countries. For example, French courts will not enforce an arbitral decision on the patent validity of a French patent but will recognize a decision on civil action for infringement.¹⁵⁵ Germany also holds that patent validity disputes are not arbitrable and therefore unenforceable by German courts.¹⁵⁶ However, countries such as the U.S. and Australia will recognize arbitral rulings on patent validity.¹⁵⁷ Finally, courts within countries such as Japan are unclear as to whether an arbitral decision on civil patent infringement and validity matters will be enforced.¹⁵⁸ Therefore, forum shopping is an important aspect of patent arbitration and the parties must be aware of the rules of each country before contractually agreeing to arbitration.

IV. UTILIZING ARBITRATION TO RESOLVE PATENT DISPUTES

Patent arbitration is a strong and viable alternative to patent litigation in resolving patent disputes in the pharmaceutical and biotechnology industries. However, while most patent disputes arising within these two industries are arbitrable, patent validity is not a recommended subject matter to be submitted to international arbitration due to the disagreements among countries as to whether arbitral holdings on patent validity should be enforced.¹⁵⁹ Parties should only arbitrate issues of patent validity when the parties are located within countries that support party autonomy to arbitrate any legal issue they choose.¹⁶⁰ However, for claims involving, *inter alia*, infringement, licensee/licensor agreements, and breach of contract, arbitration will save time and reduce costs, thereby

¹⁵² Boyd, *supra* note 35.

¹⁵³ *Id.* (noting that there are seven grounds for refusal of recognition and enforcement of an award in the New York Convention under Article V).

¹⁵⁴ *Id.*

¹⁵⁵ M.A. Smith, *Arbitration of Patent Infringement and Validity Issues Worldwide*, 19 HARV. J. OF LAW & TECH., 299, 333 (2006).

¹⁵⁶ *Id.* at 333.

¹⁵⁷ *Id.* at 320, 347.

¹⁵⁸ *Id.* at 352.

¹⁵⁹ *Id.*

¹⁶⁰ Smith, *supra* note 155, at 352.

promising a greater return on R&D and protection of a patent during its limited monopoly term.¹⁶¹ Arbitration will also protect the companies in the pharmaceutical and biotechnology industries from public scrutiny while preserving their commercial relationships, license agreements, and sensitive technical information.¹⁶² However, the efficiencies of arbitration only go as far as the parties' contractual agreement.¹⁶³ Since arbitration is a blank canvas on which the parties have complete autonomy to modify procedures to best fit their needs, the parties ought to avoid creating a patent arbitration agreement that closely resembles litigation's discovery process, judicial review, motions, and open-ended time limit.¹⁶⁴

When the parties collectively agree to write an arbitral clause that allows arbitration to resemble litigation, they are inheriting the deficiencies of litigation.¹⁶⁵ The process-enhancing techniques of arbitration are often not fully recognized as a result of the parties' and counsels' inexperience with arbitration, counsels' career experiences in primarily litigation or litigation-like proceedings, and counsels' and parties' previous prejudice to arbitration.¹⁶⁶ The College of Commercial Arbitrators created the Protocols for Expeditious, Cost-Effective Commercial Arbitration in order to aid counsel in creating a beneficial arbitral process.¹⁶⁷ The protocols suggest, among other things, that counsel and parties proactively limit discovery to the essential documents,¹⁶⁸ avoid judicial review,¹⁶⁹ limit motions,¹⁷⁰ and set time limits on arbitration.¹⁷¹ Therefore, it is a fundamental requirement for counsel to learn how to prepare appropriate arbitral clauses.

¹⁶¹ Dimock, *supra* note 34.

¹⁶² Allgeyer, *supra* note 43, at 10.

¹⁶³ Michaelson, *supra* note 1, at 3.

¹⁶⁴ Michaelson, *supra* note 1, at 3; *see also* Thomas J. Stipanowich et al., *Protocols for Expeditious, Cost-Effective Commercial Arbitration*, COLL. OF COM. ARBITRATORS (2010), at 1, 26-38, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1982169.

¹⁶⁵ Michaelson, *supra* note 1, at 3.

¹⁶⁶ *Id.*

¹⁶⁷ Thomas J. Stipanowich et al., *Protocols for Expeditious, Cost-Effective Commercial Arbitration*, COLL. OF COM. ARBITRATORS (2010), at 1, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1982169.

¹⁶⁸ *Id.* at 26.

¹⁶⁹ *Id.* at 38-42.

¹⁷⁰ *Id.* at 36.

¹⁷¹ *Id.* at 26-29.

A. Writing the Arbitral Clause

Counsel in the pharmaceutical and biotechnology industries must have a concrete understanding on how to prepare arbitral clauses that benefit their clients in patent disputes. The arbitral clause in a contract between two parties governs the entire arbitral proceeding.¹⁷² The way in which the clause is written is crucial to the success of the arbitral proceeding. There are eight commonly used elements in arbitration agreements: “(a) the agreement to arbitrate; (b) the scope of the disputes submitted to arbitration; (c) the use of an arbitral institution and its rules; (d) the seat of the arbitration; (e) the method of appointment, number and qualifications of arbitrators; (f) the language of the arbitration; and (g) a choice-of-law clause.”¹⁷³ While parties may add more elements to their agreements, the original eight should be present in order to avoid ambiguity and increase the likelihood of enforcement of the arbitral agreement.¹⁷⁴

Many institutions have model arbitral clauses to guide counsel and parties in their preparation.¹⁷⁵ For example, WIPO has an alternative dispute resolution sector that provides the following arbitral clause template:

Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. The arbitral tribunal shall consist of [a sole arbitrator][three arbitrators]. The place of arbitration shall be [specify place]. The language to be used in the arbitral proceedings shall be [specify language]. The dispute, controversy or claim shall be decided in accordance with the law of [specify jurisdiction].¹⁷⁶

While the WIPO model arbitral clause provides a beneficial starting point, there are various ways to increase its efficacy for patent disputes.

1. Recommendations for Arbitral Clauses

In order to increase the efficiency of arbitration during patent disputes for companies in the pharmaceutical and biotechnology industries, counsel should be aware of

¹⁷² Born, *supra* note 92, at 84 (“[A]rbitration generally occurs only pursuant to an arbitration agreement between parties.”).

¹⁷³ *Id.* at 85.

¹⁷⁴ *Id.*

¹⁷⁵ See *e.g.*, International Chamber of Commerce (ICC), Standard ICC Arbitration Clauses.

¹⁷⁶ WIPO, *Future Disputes: WIPO Arbitration Clause*, MODEL ADR CLAUSES.

the following potential modifications to the arbitration agreement. Arbitral proceedings are tailored to the unique relationships and circumstances of the parties thereby making it impossible to create a series of recommendations that would be beneficial in all situations. However, the following three recommendations should always be considered when drafting arbitral clauses.

First, parties should limit the scope of the arbitration agreement. The scope of the arbitration agreement governs the jurisdiction of the arbitral tribunal over the dispute.¹⁷⁷ Generally, the scope of international arbitration clauses are construed broadly in order to prevent the extra expense of parallel proceedings.¹⁷⁸ However, in cases where arbitral clauses revolve around patent disputes, the scope of the submitted disputes should be drafted narrowly. As discussed above, rulings on patent validity may not be enforceable in certain countries and a narrowly defined scope helps prevent the tribunal from ruling on issues of patent validity. Avoidance of patent validity issues is particularly important when one or both parties is a resident of a country that either does not enforce arbitral decisions on patent validity or is ambiguous on the matter of enforcement. However, removing patent validity from the scope when both parties are residents of countries that recognize arbitration decisions on patent validity can also be beneficial.¹⁷⁹ In the U.S. for example, validity decisions must be submitted to the patent office, thus rendering them public documents¹⁸⁰ thereby eliminating one of the key benefits of arbitration – confidentiality.¹⁸¹ Another alternative for parties is to keep the scope of the agreement broad, but parties can then limit the tribunal’s decision to whether or not royalties are due.¹⁸² This also effectively eliminates the chances of the tribunal ruling on validity.¹⁸³

Second, both parties should agree to an appellate arbitral review. Unless the parties agree to do so, an appeal is not available.¹⁸⁴ Appellate arbitral reviews can play an important role because of the complexity of patents in the pharmaceutical and biotechnology industries and the opportunity for large damage awards. In fact, these industries have the highest median damages awards rendered in litigation.¹⁸⁵ Courts have

¹⁷⁷ Born, *supra* note 92, at 86.

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ Allgeyer, *supra* note 43, at 10.

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.* at 9.

¹⁸⁵ Barry, *supra* note 51; *see also*, Bayer CropScience AG v. Dow AgroSciences LLC, No. 2:12cv47, 2012 U.S. Dist. LEXIS 97850 (E.D. Va. Jul. 13, 2012) (explaining that subsequent arbitration found that Dow owed Bayer \$456 million in damages and other costs, subject to a daily interest rate of 8%).

a limited ability to vacate or annul arbitral awards;¹⁸⁶ therefore, companies within these industries would find it beneficial to establish a secondary tribunal to review the arbitral award and modify it if necessary.¹⁸⁷ This method safeguards companies from having to pay unreasonably large sums in damages.

Lastly, because the details of a patent are sensitive, especially in industries where reverse engineering is a threat to products, parties should include a confidentiality agreement. This agreement will bind the parties to secrecy and prevent them from leaking to the public important information on finances, patent technology, the proceedings, and more.¹⁸⁸ Confidentiality agreements can be signed post dispute but it is best for the parties to mutually agree to secrecy before a dispute arises in order to ensure neither party releases confidential information prior to signing such an agreement.

2. *Sample Arbitral Agreement*

This sample arbitral agreement was created through the aid of WIPO's model arbitration clause, the International Bar Association's Guidelines for Drafting International Arbitration Clauses, and the American Health Lawyers Association's ("AHCA") Guide to Arbitration Clauses. Importantly, whenever parties create an arbitral clause, the initial clause should follow the template of the institution through which the parties choose to arbitrate, if they choose to arbitrate through an institution at all.¹⁸⁹ In the following example, the first paragraph is a clause which does not follow any institutional template.

All [disputes][controversies][claims] arising out of or in connection with this contract, including any questions regarding its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be referred to and finally determined by arbitration in accordance with [institutional rules]. The following matters are specifically excluded from arbitration hereunder: questions regarding patent validity.

The arbitral tribunal shall consist of three arbitrators, one selected by the claimant in the request for arbitration, the second selected by the respondent within [time] of receipt of the request for arbitration, and the third selected by the claimant and the respondent within [time] of the selection of the second arbitrator. If any arbitrators are not selected within these time periods, [the designated institution] shall, upon the request of any party, make the selection(s).

The place of arbitration shall be [place]. The language to be used in the arbitral proceedings shall be [language]. The

¹⁸⁶ Born, *supra* note 92, at 1134 (listing the limited number of circumstances described in national arbitration legislation where a court is permitted to annul an arbitral award).

¹⁸⁷ Michaelson, *supra* note 1, at 5.

¹⁸⁸ Allgeyer, *supra* note 43, at 10 ("Parties are not automatically sworn to secrecy.").

¹⁸⁹ INT'L BAR ASS'N, *IBA Guidelines for Drafting Int'l Arb. Clauses*, 7 (2010).

[dispute][controversy][claim] shall be decided in accordance with the law of [jurisdiction]. The procedure to be followed during arbitration shall be agreed by the parties within [time] or, failing such agreement, determined by the arbitral tribunal after consultation with the parties within [time].

Within [time] after an award is issued on the [dispute][controversy][claim], a party may file an appeal with a second arbitral tribunal. Within [time] after such an appeal is filed, any other party may file a response or a cross appeal. Once an appeal is filed, no party will pursue an action in court to vacate, modify or enforce the award. The tribunal shall consist of [one arbitrator selected by the claimant and the respondent within [time] after filing of the appeal][three arbitrators, one selected by the claimant in the request for appeal, the second selected by the respondent within [time] of receipt of the request for appeal, and the third selected by the claimant and the respondent within [time] of the selection of the second arbitrator]. The review shall be in accordance with the [institutional rules chosen above]. The place of appellate arbitration shall be [place]. The language to be used in the arbitral proceedings shall be [language]. The [dispute][controversy][claim] shall be decided in accordance with the law of [jurisdiction].

The existence and content of the arbitral proceedings and any rulings, awards, testimonies or materials shall be kept confidential by the parties and members of the arbitral tribunal except (i) to the extent that disclosure may be required of a party to fulfil a legal duty, protect or pursue a legal right, or enforce or challenge an award in *bona fide* legal proceedings before a judicial authority, (ii) with the consent of all parties, (iii) where needed for the preparation or presentation of a claim or defense in arbitration, (iv) where such information is already in the public domain other than as a result of a breach of this clause, or (v) by order of the arbitral tribunal upon application of a party.¹⁹⁰

This sample arbitral agreement is beneficial for parties dealing with a patent dispute because it contains the suggested modifications of a limited scope by requiring issues of patent validity to not be submitted to arbitration, an agreement for an appellate arbitral review, and a confidentiality provision. It also suggests the use of a three party tribunal for the initial arbitral review given the typically technical and complex nature of patented inventions in the pharmaceutical and biotechnology industries. Lastly, the clauses specify time constraints on the parties and the tribunal in order to aid in the reduction of time spent disputing a conflict and costs. As with all arbitral agreements, parties should work diligently to tailor the agreement to their specific needs and relationship despite the constraints and recommendations found within any template.

¹⁹⁰ The model clause was created through the aid of WIPO's model arbitration clause available at WIPO, *Future Disputes: WIPO Arbitration Clause*, MODEL ADR CLAUSES; INT'L BAR ASS'N, *IBA Guidelines for Drafting International Arbitration Clauses*, (2010); and AHLA, *Guide to Arbitration Clauses*, DISPUTE RESOLUTION SERVICE.

V. CONCLUSION

International arbitration is an underutilized method of patent dispute resolution. However, the biotechnology and pharmaceutical industries are well suited for patent arbitration and would benefit from implementing this alternative form of international dispute resolution in place of international litigation. Pharmaceutical and biotechnology companies should seize the opportunity to arbitrate patent disputes to save time and costs, protect trade secrets and commercial relationships, and avoid unreasonable jury awards. Litigation is a one-size-fits-all process that, even in the face of particular benefits, is ultimately an arduous, expensive, and inefficient process that has the potential to harm parties seeking to enforce their patent rights. By contrast, arbitration can provide the same benefits as litigation more quickly and at considerably less cost while preserving flexibility and confidentiality. If parties and counsel take the time to learn how to create arbitration agreements that fit their needs while avoiding a litigation-like process, they will begin to recognize the returns of international arbitration that companies in the commercial realm have reaped for years. By following the recommendations in this article, companies within the pharmaceutical and biotechnology industries will effectively protect their patent rights internationally while avoiding the complexities and inconsistencies of international litigation. International patent arbitration has the potential to be a viable future for dispute resolution in these two universally important and indispensable industries.