A Compilation Of Practitioners' Views—Life Sciences Dispute Resolution

By Judith Schallnau

This *Compilation of Practitioners' Views on Life Sciences Dispute Resolution* was prepared in light of increasing numbers of life sciences mediations and arbitrations filed with the WIPO Arbitration and Mediation Center (WIPO Center), and in conjunction with a WIPO Center Conference on Dispute Resolution in Life Sciences held on May 22, 2015, in Basel, Switzerland. It serves to assess the current use of Alternative Dispute Resolution (ADR) processes and court litigation in life sciences disputes, as well as to shed light on party dispute resolution strategies and best practices in this area. These issues will be discussed at the WIPO Center 2016 Conference on Life Sciences Dispute Resolution.[1] The principal comments relate to the types of life sciences disputes arising, to tailoring arbitration and mediation proceedings to meet life sciences dispute resolution needs, how disputes are resolved, at what time and cost, and trends.

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The Compilation was written in collaboration with a WIPO Center-appointed Working Group on Life Sciences Dispute Resolution. This Working Group comprised seasoned in-house counsel and external practitioners working in the pharmaceutical sector, diagnostics, biotechnology, medical devices, related research and development, and in other life sciences industry areas in countries constituting large markets for these sectors.[2] They shared their dispute resolution experiences, and identified related trends. As the Compilation is based on individual experiences in specific instances, it does not attempt to provide a comprehensive overview of disputed matters in life sciences, or ways to handle them.

I. Life Sciences Disputes

When asked about their or their clients' involvement in life sciences disputes in past years, most Working Group members stated that they/their clients have mainly been involved in international disputes, including in Asia, Europe and the United States of America. Most disputes took place in multiple jurisdictions since they often concerned collaborations or conflicts between parties based in different countries, and IP protected on a national level but disputed in a number of countries.

Such disputes involved companies of different sizes, research institutes, universities, scientists/inventors and agents active in various fields of life sciences (including pharmaceuticals, medical devices, biotechnology or veterinary drugs).

Some Working Group members were largely (up to 90 percent) involved in *non-contractual* disputes between originator companies, and between originator and generics companies. Their *contractual* disputes were based on different types of agreements such as development, joint R&D, license, know-how, settlement, co-promotion or distribution agreements, as well as agency and research contracts.

1. Further information is available at: *http://www.wipo.int/amc/en/events/*.

2. On behalf of the WIPO Center I wish to express its gratitude to the Working Group members (listed in alphabetical order) who provided most valuable input to this Compilation, namely: Pravin Anand, Partner, Anand and Anand Advocates, India; Håkan Borgenhäll, Partner, Vinge, Sweden; Thierry Calame, Partner, Lenz & Staehelin, Switzerland; Trevor Cook, Partner, Wilmerhale, United States of America; Jürgen Dressel, Head of Patent Litigation, Novartis, Germany; Joachim Feldges, Partner, Allen & Overy LLP, Germany; Javier Fernández-Lasquetty, Partner, Elzaburu, Spain; Alejandro I. Garcia, Senior Associate, Winston & Strawn, United Kingdom; Penny Gilbert, Partner, Powell Gilbert LLP, United Kingdom; Michael Gross, Head Licensing Department, Fraunhofer-Gesellschaft, Germany; Ulf Johann, Legal Counsel EU grants, Fraunhofer-Gesellschaft, Germany; Rachael Kent, Partner, WilmerHale, United States of America; Beomsu Kim, Partner, Shin & Kim, Republic of Korea; Klaus Kupka, Partner, Taylor Wessing, Germany; Lalive (firm feedback provided by Domitille Baizeau, Partner, Laura Halonen and Thomas Widmer, Associates), Switzerland; Catherine Eunkyeong Lee, Partner, Bae, Kim & Lee, Republic of Korea; Russell E. Levine, Partner, Kirkland & Ellis LLP, United States of America; Thiess Matzke, Senior Legal Counsel, Ascenion, Germany; Amandine Métier, Partner, Véron & Associés, France; Peter Michaelson, Attorney, Arbitrator and Mediator, United States of America; Miquel Montañá, Partner, Clifford Chance Barcelona, Spain; Kevin Nachtrab, Senior Legal Counsel, Johnson & Johnson, Belgium; Douglas R. Nemec, Partner, Skadden, Arps, Slate, Meagher & Flom LLP, United States of America; Verena Neuhold, Legal Counsel, Roche Diagnostics International AG, Germany; Yoichi Okumura, Global Head of IP, Takeda Pharmaceutical Company, Ltd., Japan; Bert Oosting, Partner, Hogan Lovells International LLP, The Netherlands; David PERKINS, Arbitrator and Mediator, United Kingdom; Jane Player, Partner, King & Spalding, United Kingdom; Sabine Rojahn, Partner, Taylor Wessing, Germany; Sally Shorthose, Partner, Bird & Bird LLP, United Kingdom.

In addition to the purely commercial disputes, contentious *matters* also related to the achievement of milestones, IP issues (in particular patent validity and infringement cases), supplementary protection certificates, trademark and design rights, inventor's rights, breach of confidentiality obligations, regulatory matters, data exclusivity, and various other matters, such as comparative consumer-directed advertising or the acquisition of start-up companies.

The *remedies* mentioned include injunctions, damages, declarations of infringement/invalidity, other declaratory remedies, indemnities, payment of commissions, the sale or distribution of medical devices or pharmaceuticals, the use of confidential information and the breach of non-compete obligations. (See case examples below.)

To date, 15 percent of mediation and arbitration cases filed with the WIPO Center relate to life sciences. These arbitrations or mediations related, for example, to distribution agreements for generic drugs, development agreements concerning pharmaceutical products, the renegotiation of license agreements and payment obligations of royalty rates, settlement agreements of prior litigation in several countries, the exercise of option agreements, supplemental protection certificates (SPCs), the performance of distribution agreements, trademark licenses, supply agreements, and co-promotion agreements for pharmaceutical products.

Non-contractual disputes related to the infringement and (in-)validity of patents, trademarks and design. Procedural issues in such WIPO cases included questions in multi-party arbitrations involving legal succession, challenges of party-nominated arbitrators, privilege and confidentiality obligations, and bifurcation of proceedings.

The parties to these cases were based in Asia, Europe and the United States of America. Different types of entities were involved: research institutes, pharmaceutical companies, universities, university hospitals, and small and medium-sized companies working in biotechnology and medical devices. While the cases varied in complexity, the largest amount in dispute was USD 1 billion.

II. Dispute Resolution Needs in Life Sciences

Working Group members considered the following factors to be particularly important for life sciences dispute resolution:

The need to *keep disputes confidentia*l was highlighted, in particular if background inventions and know-

The Following Case Examples Illustrate The Variety Of Life Sciences Disputes:

- **An inventor licensed out a technology to a company. The company continued developing the technology. A dispute arose as to whether the developments constituted improvements of the invention and whether they fell within the scope of the license, particularly in light of royalty payment obligations.**

- **An international Europe-based pharmaceutical company and a Belgian start-up company collaborated in the development and commercialization of a technology to manufacture drugs. The technology was patented and an agreement between the parties defined the scope of authorized use by the parties. The interpretation of the contract (permitted use of technology) and claim construction of the patents were at the heart of a complex technical dispute arising a few years later. The parties commenced arbitration proceedings and settled the case at a later stage.**

- **A European pharmaceutical company initiated preliminary injunction and infringement proceedings against several generics companies on the basis of a supplementary protection certificate. Court proceedings took place in several European countries, and involved national courts referring questions on the interpretation of Regulation (EC) 469/2009 about supplementary protection certificates to the Court of Justice of the European Union. The dispute terminated after two years.**

- **An Asian innovator company has been involved in patent infringement lawsuits against generics companies in the United States of America. Under the Hatch-Waxman Act a generics company filed abbreviated new drug applications (ANDAs) for the innovator's pharmaceutical drugs in order to get early access to the market by certifying that the innovator's patent was invalid. In accordance with the applicable law, the Asian company commenced court litigation on the alleged issues.**

- **A Hatch-Waxman litigation before the Eastern District Court of New York involving multiple parties was referred to mediation. For the purpose of the mediation the cases were consolidated into one proceeding between the originator company and the generics companies. Considerable progress towards a settlement was made. Shortly before settlement was reached after six months of negotiations (including a two-day hearing and exchange of detailed documents at a mediator's fee of USD 80,000), one party infringed the confidentiality of the mediation while being acquired by a third party. Court litigation continued.**

how are involved, and for reputational reasons.

Availability of preliminary injunctions was considered essential, including in circumstances where market exclusivity needs to be preserved.

Another important need mentioned was the *expertise of the decision-maker* in litigation and arbitration. Given the high level of specialization of life sciences industry areas, judges and arbitral tribunals should have relevant legal understanding, including regulatory matters, competition law issues, and commercial understanding. Such knowledge was considered to be essential as life sciences disputes are often highly complex and technical, with commercial issues, IP and regulatory matters interlinked and parallel proceedings taking place in several countries. An experienced decision-maker, who can guide the parties on procedural matters, was considered useful in such circumstances. By the same token, it was considered essential to have a mediator with technical expertise who could offer meaningful assistance to the parties in mediation.

The need to *preserve business relationships* was considered particularly important in light of the parties' expert knowledge (*e.g.*, scientists involved, and the desired longevity of many research and commercial collaborations).

Contractual and non-contractual *disputes should be anticipated*: while dispute resolution provisions are often regarded as a relatively minor element in contract negotiations, Working Group members emphasized the need to make a considered choice of dispute resolution mechanisms. Also, anticipating non-contractual disputes can involve monitoring relevant markets to react quickly, (*e.g.*, in case of disputes between originator and generics companies when a generic drug is launched.) Vice versa, when companies intend to launch products, they should anticipate disputes impairing their business activities in a particular market.

Other issues included cost and length of proceedings, the need for a broader resolution of the dispute, especially in long-term collaborations, the enforceability of the outcome, the neutrality of the decision-maker or the forum where the dispute would need to be settled, having a single forum for resolving a dispute (which would otherwise have to be resolved in different fora), and on the finality of the dispute.

III. Tailoring ADR Proceedings to Meet Parties' Dispute Resolution Needs

Mediation and arbitration afford parties the opportunity to exercise greater control over the way their dispute is resolved than would be the case in court litigation.

While the flexibility of ADR and its advantages were said to be not so well-known in the life sciences area, Working Group members welcomed an informed and considered process design with, most importantly, carefully chosen mediators and arbitrators familiar with the relevant life sciences legal, technical and/or business area. Some considered it particularly useful to make specific provisions regarding evidence (including details about experiments), access to samples and testing, or determining the scope of discovery, selecting suitable technical and damages experts, and witnesses. Further, choosing an arbitral institution with active case management, and having arbitration rules allowing for maximum party autonomy, confidentiality and tribunal-appointed experts, was considered important.

The possibility of *combining mediation with other procedures* was highlighted (*e.g.*, mediation followed, in the absence of a settlement, by [expedited] arbitration/by court litigation), to define the way forward.

"In-Life" Mediation

A UK-based IP lawyer explained that she uses with some of her life sciences clients what they call "in-life" mediation: before the main contract is negotiated, or even before a non-disclosure agreement is concluded, the parties to contract negotiations agree, often in the form of a memorandum of understanding, the reasons why they want to collaborate, and their interests and needs of each other in the commercial venture. They then agree in the contract that they will appoint a neutral to live with the life of the agreement, whose role would be to facilitate negotiations, to meet with the parties, if either party gives notice, and to remind them of their MOU and the interests and needs first identified to justify the joint relationship. The role is intended to help when problems arise and is time limited, usually to 30 days. At this stage, the MOU terms, rather than the contractual rights, are the priority. If a resolution is not reached or if the relationship is not put back on track, then the normal mediation, arbitration, litigation or dispute board clause is triggered in the contract. This has proven useful to assure parties who share confidential—often highly valuable—information before and after the signing of a contract that they have the assistance of a neutral third person in case of discrepancies related to such information, or any other issues arising out of the relationship. In the dispute resolution clause of the main contract, parties may agree to continue using mediation or another form of ADR after the agreed time period for "in-life" mediation.

In most WIPO cases, parties use the recommended WIPO contract clauses and submission agreements without amendments (*http://www.wipo.int/amc/en/clauses/index.html*). However, sometimes parties introduced modifications, based on careful drafting and

guidance by experienced legal practitioners, and, at times, further to consulting with the WIPO Center.[3] The following case examples illustrate some sophisticated process design, and include the unusual introduction of an appeal stage in the arbitration to address life sciences parties' concerns about the finality of arbitration in relation to very valuable patents.

Complex Patent Arbitration

Following litigation in several jurisdictions regarding the alleged infringement of European and U.S. patents protecting medical devices, a European company and an American company signed a settlement agreement including a WIPO arbitration clause.

Given the importance of the patents in dispute for the parties, they amended the standard WIPO arbitration clause so that under the clause, infringement claims of U.S. patents should be heard by a sole U.S. arbitrator, and those relating to European patents by a sole European arbitrator. The clause further provided that the awards issued by the European and the U.S. arbitrator could be subject to review through an appeal panel of three arbitrators.

A year after the signing of the settlement agreement, the European company commenced WIPO arbitration proceedings, claiming infringement of its U.S. and European patents. From a list of candidates submitted by the Center, the parties agreed on a patent law specialist from the U.S. and a patent law specialist from Europe to consider the allegations of infringement of the U.S. patents and the European patents respectively. The parties agreed on a procedural order setting out the procedural steps, including the use of the WIPO Electronic Case Facility, the timetable for the proceedings, the scope of discovery, a protective order, the preliminary claim construction of the U.S. and European patents, and a hearing schedule.

The U.S. arbitrator and the EU arbitrator issued their awards within 18 months of their appointment. The parties agreed not to use the appeal procedure.

3. Where deemed useful, parties can adapt model clauses and submission agreements to their further needs. For such specific cases, the WIPO Center developed a Clause Generator which proposes additional elements based on WIPO case experience: *http://www.wipo.int/amc-apps/clause-generator/*.

Submission of a Patent Dispute to Arbitration

Following litigation in several jurisdictions, two American companies agreed to submit to WIPO Arbitration a dispute related to the alleged infringement of a European patent on consumer goods. The submission agreement provided that the national patent law of a particular European country would apply and that the patent litigation timelines of that country should be followed. The three-member tribunal was asked to decide whether the manufacture and sale of certain products infringed the patent.

The submission agreement, and compliance with the procedural timetable in the subsequent arbitration process, reflected the parties' mutual wish to resolve the dispute in a time and cost-efficient manner. The parties accepted the Center's recommendation to appoint three arbitrators with substantial expertise in arbitration and in the relevant national patent law. Further to the exchange of written submissions, the arbitral tribunal held a one-day hearing for further statements and for the examination of expert witnesses. In accordance with the time schedule agreed by the parties, the final award was rendered within five months of the commencement of the arbitration.

IV. How Disputes Are Resolved

Working Group members explained that they/their clients used court litigation, arbitration and mediation to resolve national and cross-border disputes in a frequency corresponding, broadly speaking, to their knowledge of, and familiarity with, these dispute resolution options. While court litigation was most frequently chosen, Working Group members emphasized the complexity of preparing and coordinating parallel litigation to comply with different legal systems (*e.g.*, pre-grant opposition procedure in India, bifurcated patent litigation in countries such as Germany).

Arbitration (particularly in cross-border agreements) was also said to be frequently chosen, whereas the opportunity to use mediation seems to be still underexplored. However, Working Group members, both in-house and external counsel, described an increasing willingness to choose mediation, as it allows management to exercise a determining influence on the dispute resolution process, and to find solutions addressing business interests.

Disputes Involving Biosimilars

A Working Group member pointed out that while patent litigation between originator and generics companies is well-known, patent litigation involving biosimilars is largely new territory. Compared with generic drugs, different issues arise when biosimilars are concerned. Biosimilars are very complex to manufacture and involve relatively high development costs, with fewer and fewer [or an increasingly small number of] companies or research institutions being able to manufacture them. These factors lead to a competitive environment which is very different from the one involving generics companies. For the latter, other Working Group members indicated that with fewer blockbuster patents, generic litigation is likely to decrease.

The following two WIPO mediation case examples illustrate how commercial mediation can be used for disputants' benefit:

Mediation of a Pharma Patent License

A European university holding pharmaceutical patent applications in several countries negotiated a license option agreement with a European pharmaceutical company. The pharmaceutical company exercised the option and the parties started to negotiate a license agreement. After three years of negotiations, the parties were unable to agree on the terms of the license. At that point the parties submitted a joint request for WIPO mediation. As requested by the parties, the Center appointed as mediator a lawyer who had worked in the pharmaceutical industry for many years and who had considerable licensing experience. The parties requested that the mediator help them reach an agreement on the terms of the license. The one-day meeting session allowed the parties to identify the issues and deepen their understanding of the legal circumstances. On this basis, the parties continued direct negotiations amongst themselves and reached a settlement agreement.

Mediation of a Biotech Dispute

A French and a German company entered into a collaboration agreement for the development of a human antibody for the treatment of a major disease. Two years later, a U.S. corporation acquired the French company. Alleging that the U.S. corporation shortly thereafter caused certain payments required under the collaboration agreement to be withheld, the German entity filed an action for breach of contract against the U.S. corporation in a district court in the United States. The U.S. corporation filed counterclaims of rescission and breach of contract against the German company. After more than a year of court proceedings, the parties accepted the judge's suggestion to submit their dispute to mediation and they filed a joint request for mediation with the Center.

The mediator, an American IP lawyer, conducted meetings with the parties in the United States. As a direct consequence of the facilitative role played by the mediator, the parties settled their dispute six months after the commencement of the mediation.

V. Duration and Cost of Life Sciences Dispute Resolution

The members of the Working Group named time and costs as key issues in any dispute involving pharmaceuticals and other life sciences. Table 1 summarizes their experience of how long patent litigation proceedings take in selected countries, and how much it costs per patent. (The numbers are based on individual experience in limited instances and will, naturally, differ from case to case.)

By comparison, so far, WIPO mediations in the area of life sciences took between four and seven months and cost between USD 16,000 and USD 49,000. WIPO arbitrations, including complex cases related to technologies protected by patents in a number of jurisdictions with lengthy and costly evidentiary procedures, took on average 22 months and cost on average USD 234,000.

VI. Trends

The Working Group members were asked about trends in the development of technology or of business practices in the life sciences sector which may influence their/their clients' choice of dispute resolution mechanisms.

Some mentioned an increase in *outsourcing* of originating development work to universities, university spin-offs and contract research organizations. The entities conducting research were likely to avoid the risk of costly court litigation and to opt instead for what is perceived to be the more private and less costly mediation and/or arbitration alternative

Table 1 - Patent Life Sciences Litigation in Selected Jurisdictions

Country	Characteristic of Legal System	Competent Courts	Average Length	Average Cost
Brazil	Civil Law Unified Litigation Specialized courts	First Instance Court of Appeal Superior Court of Justice Supreme Federal Court	2-4 years 1-3 years 1-3 years 1-3 years	USD 50,000-1 Mio USD 20,000-150,000 USD 10,000-300,000 USD 10,000-300,000
China	Civil Law Bifurcated Litigation Specialized courts	Specialized IP Courts* Higher People's Court Supreme Court Intermediate Court** Higher People's Court Supreme Court *Beijing, Shanghai, Guangdong **Other provinces	1-2 years* 6 months-1 year* 6 months-1 year 1-2 years* 6 months-1 year* 6 months-1 year	USD 150,000-250,000 USD 100,000-150,000 USD 100,000-300,000 USD 150,000-250,000 USD 100,000-150,000 USD 100,000-300,000
France	Civil Law Unified Litigation	Tribunal de Grande Instance, Paris Court of Appeal, Paris Supreme Court	18 months 2 years 18 months	EUR 200.000-500.000 EUR 150.000-375.000 EUR 50.000
Germany	Civil Law Bifurcated Litigation Specialized courts	*Infringement:** Regional Court Higher District Court Federal Supreme Court *Invalidity:** Federal Patent Court—Revocation Chamber Federal Supreme Court *Value in dispute: 1Mio-15Mio	 6-12 months 12-18 months 18-24 months 18-24 months 20-24 months	 EUR 80,000-650,000 EUR 90,000-765,000 EUR 115,000-1 Mio EUR 85,000-740,000 EUR 105,000-880,000
India	Common Law Unified Litigation	District Court High Court Supreme Court	3-5 years 3-5 years 3-5 years	EUR 25,000-150,000 EUR 20,000-500,000 EUR 20,000-100,000
Japan	Civil Law Unified Litigation Specialized courts	District Court IP High Court Supreme Court	15.7 months 6.7 months 12.5 months	USD 100,000-1 Mio USD 50,000-100,000 USD 50,000-100,000
Republic of Korea	Civil Law Bifurcated Litigation Specialized courts	*Infringement:* District Court High Court Supreme Court *Invalidity:* Patent Tribunal Patent Court Supreme Court	 12-18 months 12-18 months 6-24 months 10-12 months 12-18 months 6-24 months	 USD 50,000-200,000 USD 50,000-300,000 USD 50,000-500,000 USD 10,000- -50,000 USD 50,000-300,000 USD 50,000-500,000
Russia	Civil Law Bifurcated Litigation Specialized courts	First instance court Appellate court (First Appeal) IP court (Second Appeal) Supreme Court	6-9 months 2-3 months 3-4 months 5-12 months	USD 60,000-80,000 USD15,000-25,000 USD15,000-25,000 USD 5,000-17,000
Spain	Civil Law Unified Litigation	Court of First Instance Court of Appeal Supreme Court	12-18 months 12-18 months 2-3 years	EUR 75,000-200,000 EUR 50,000 EUR 50,000
Sweden	Civil Law Unified Litigation	Stockholm City Court Court of Appeal Supreme Court	12-18 months 1 year 1 year	EUR 150,000 EUR 100,000 EUR 75,000
Switzerland	Civil Law Unified Litigation Specialized courts	Swiss Federal Patent Court Swiss Federal Supreme Court	Nullity: 1.5 years; Infringement: 2 years; Preliminary injunction: 4 months-1 year 6-8 months	CHF 100,000-150,000 CHF 100,000-300,000 CHF 80,000-160,000 CHF 40,000-80,000
The Netherlands	Civil Law Unified Litigation Specialized courts?	District Court of The Hague The Hague Court of Appeal Supreme Court	10-12 months 14 months 18 months	USD 200,000 USD 175,000 USD 125,000
United Kingdom	Common Law Unified Litigation Specialized courts	Intellectual Property Enterprise Court (IPEC) Patents Court—Chancery Division of the High Court Court of Appeal of England and Wales Supreme Court	12-18 months 12-18 months 12 months 18-24 months	USD150,000-250,000 USD 800,000 USD 400,000 USD 400,000
United States of America	Common Law Unified Litigation Specialized court of appeal Jury trial	District Courts Court of Appeals for the Federal Circuit Supreme Court USPTO—PTAB Inter Partes Review Post Grant Review	24-40 months 1 year 1 year 18 months from filing 18 months from filing	USD 4-6 Mio USD 1 Mio USD 1 Mio USD 500,000-600,000 USD 500,000-600,000

Source: A Compilation of Practitioners' Views—Life Sciences Dispute Resolution, les Nouvelles, September 2016.

Working Group members employed with a European research institution stated that the institution uses a standard dispute resolution clause for international cooperation agreements with industry, licenses and third-party funded projects industry. This template provides for direct negotiations, followed by WIPO Mediation followed by WIPO Expedited Arbitration and is used, *e.g.*, in nearly all licensing agreements. They confirmed a high willingness to settle conflicts out of court in third-party funded projects to make best use of the time and funding available.

Several Working Group members confirmed a *trend to settle* in court litigation, as well as in arbitration. Reasons for this included the need to save costs and to preserve party reputation. In particular, smaller entities were said often to avoid court litigation because of its high costs and the related risk for their overall business activities.

A U.S. lawyer stated the following about *developments of electronic discovery*:

"Electronic discovery expenses can be crushing in complex IP disputes—I would say they constitute the single largest expense in any given case (more even than trial in many cases).

[…] [D]evelopments in electronic discovery technology are having mixed effects on the appetite of companies to engage in complex litigation. On the one hand, technologies such as predictive coding can ease some of the burdens associated with reviewing large volumes of electronic documents. On the other hand, technologies for storage and recovery for electronic data, and concerns about deletion of electronic data, are causing a proliferation in the volume of data that may counteract the benefits of review technologies. On balance, I believe that without dramatic change to court rules regarding discovery of electronic data, litigation in U.S. courts could become unduly expensive for resolution of many disputes in coming years."

In terms of using ADR mechanisms, some Working Group members observed that contractual agreements mainly stipulate that arbitration should be used as a dispute resolution mechanism.

However, they stated that an *increased use of mediation* can be observed, possibly fostered by national courts mandating or encouraging mediation. In particular, many U.S. district courts mandate mediation and the national courts in European Union Member States may, in particular further to the implementation of *Directive 2008/52/EC of the European Parliament and of the Council of 21 May 2008 on certain aspects of mediation in civil and commercial matters,* encourage parties to use mediation. Working Group members stated that mediation has become a more generally accepted management tool increasingly acceptable to, and encouraged by, businesses. Key arguments were again time and costs: as management was reported to be less and less prepared to engage in long, drawn-out costly multi-jurisdiction court litigation, businesses were said to be more amenable to using international mediation and arbitration as alternatives to court litigation.

An Indian IP practitioner stated that court-annexed mediation is increasingly used in India:

"Even if there is a small chance of settling the matter, the courts prefer to explore the possibility by referring the matter to mediation. In view of the same, parties should not refuse mediation and make an earnest effort to settle the matter as not doing so may prejudice the judge against that party. […] In our experience, we have seen that matters between a big party and a smaller party are more likely to get settled through mediation than disputes between two big parties. […] Even between two big parties, we have observed that the main reason for the breaking of the mediation is because of the insistence of payment of damages by the Plaintiff. […] If the mediation is successful and ends in a settlement between the parties, the court's fee is refunded to the Plaintiff."

Another issue mentioned was the increased use of inter partes review (IPR) created by the America Invents Act in 2011, which allows challenges to patents before the USPTO's Patent Trial and Appeal Board (PTAB). IPR typically takes between 12 and 18 months. While proceedings before the PTAB are pending, Hatch Waxman proceedings may be initiated by (another) generics company and the originator company may commence court proceedings. These take typically 30 months. A concern raised was insecurity about the potential impact of the PTAB decision, which is likely to be rendered before the court decision, on the latter.[4]

4. The WIPO Center is one of the listed dispute resolution services providers for Trademark Trial and Appeal Board (TTAB) and PTAB proceedings: *http://www.wipo.int/amc/en/center/specific-sectors/ipos/.*

A number of Working Group members mentioned uncertainty about the future operations of the Unified Patent Court (UPC). In particular, some Working Group members were concerned about the effects of the so-called "opt-out": during a transitional period of seven years, European patents can be litigated before the national courts and before the UPC, unless the patent owner chooses to opt out of the competence of the UPC. Questions raised relate to the timing of such opt-out, and the possibility to withdraw it. Some Working Group members indicated that patentees are likely to opt out with a view to protecting valuable patents.

Others mentioned a risk of pan-European injunctions being granted and uncertainty about the criteria applied for the grant of injunctions. For commercial activities questions arise, for example, about patent portfolio management and licensing. Given that a European patent and a Unitary Patent could be revoked in their entirety in a proceeding before any participating EU Member State, patent owners will need to monitor and decide carefully the countries in which they want to maintain their patent rights. Further, the licensor may wish to discuss the opt-out decision with licensees as they would be affected by an overall Unitary Patent/European patent invalidation and would need to monitor more extensively litigation activities in all relevant countries. Also, dispute management and (exclusive) licensees' rights to litigate were issues mentioned for consideration.

In light of these open questions, some Working Group members stated that mediation or arbitration may be increasingly attractive options, as they allow more predictable procedures and party-tailoring of dispute resolution processes. ■

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http://ssrn.com/abstract=2822266