Managing disputes in the life sciences

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Life sciences company decision-makers can effectively manage disputes using appropriate dispute resolution techniques without resorting to expensive, complex, and uncertain litigation.

Innovation is fraught with dispute, and the life sciences are no exception. Academics fall out with their industry sponsors and with one another, joint ventures fail, competitors steal trade secrets and infringe patents, and experimental drugs fail after years of research and substantial investment. However, very few disputes are litigated, and far fewer, only about 1–2% of lawsuits filed in the United States, result in a judgment on the merits[1]. In most instances, litigation is a poor option for technology companies. It is inherently slow, expensive, complex, and uncertain even under the best of circumstances. For instance, in patent cases alleging infringement in England and Wales, there is a 41.8% chance an asserted patent will be revoked, and an even smaller chance it will be found valid and infringed[2]. Getting to this unhappy result for claimants usually takes more than a year and costs more than a million dollars.

Company decision-makers therefore need the skills and tools to effectively manage disputes without resorting to litigation. In this respect, it is critical to understand and appreciate more than the legal merits of a potential case. Future business concerns, national or cultural biases, commercial relationships, as well as the subjective nature of a dispute may be more important considerations.

This article examines some areas of common disputes in the life sciences and proposes considerations and techniques for effective conflict resolution. It then discusses appropriate dispute resolution (ADR) as a complement or alternative to litigation, and how ADR could be used more efficiently by life sciences entities, whether start-ups, tech transfer offices, biopharmaceutical or med-tech small and medium-sized enterprises, or multinationals.

Recurring disputes in the life sciences

Certain types of disputes frequently recur in the life sciences (**Table 1**). Imagine, for example, a new monoclonal antibody has been shown to be effective at treating ulcerative colitis as a result of a research collaboration between two principal investigators (PIs) at different universities. The research was funded by a grant from a national body, such as the National Institutes of Health or the European Commission, and the new antibody is a derivative of an antibody licensed to one of the PIs by a biotech company under a material transfer agreement.

It is easy to envisage all sorts of conflicts arising from such a scenario. There may be disputes related to ownership of the derivative antibody and access to the research results. In an ideal world, the parties would have worked out all potential ownership and access issues previously. That does not always occur. It may be the case that not all of the inventors are under assignment obligations—an academic may be working independently from their institution, an inventor's name may be left out for a variety of reasons, or a contract may not have been properly formed. Contracts may fail to make provision for changes in the scope of research, division of responsibilities, access to biological materials, and subsequent conduct of parties.

Some contracts, such as licensing agreements between partnering organizations, can be enormously complex. For instance, a university may agree to license its ownership interest under 'commercially reasonable' or 'mutually agreed upon' terms or based on market royalty rates. That may be fine when no revenue is being generated, but in the event that a new antibody

Table 1 Common subjects of life sciences disputes

Licensing
R&D agreements
Inventorship and ownership
Royalties and IP valuation
Technology transfer
Patent infringement
Trade secret misappropriation
Derivatives
Access to ancillary IP such as regulatory filings

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Table 2 Checklist for dispute resolution

Legal merits
Facts
Laws
Jurisdiction and venue
Positions
Litigation costs
Procedural issues and discovery/disclosure of information
Available remedies
Likelihood of recovery
Business considerations
Importance of ongoing relationship with defendant
Internal drain on company resources
Consequences of 'loss' or 'victory'
Opportunity costs
Reputational costs
Impact on budgets and cash flows
Time
Propensity for further conflict escalation
Interpersonal or cultural considerations
Emotions
Beliefs
Values
Access to third-party financing
Contingency/success fees
ADR
Engaging neutral parties
Timing
Budget
Relevant experience
Ability to combine processes cost-effectively (e.g., mediation with arbitration)

turns into a blockbuster biologic, a difference of a fraction of a percent in a royalty rate becomes significant. At which point, it becomes challenging to say what would have been commercially reasonable in hindsight. Alternately, it may be vital for a biotech company to 'own' the underlying intellectual property (IP) so that it can allow a lien on its IP to raise financing, but tech transfer offices may insist on IP ownership as a matter of principle or tradition. For that matter, a company may be restricted in the extent to which it can exclude others from using a technology if a public authority grant provides obligations related to patent ownership, open licensing, or commercialization.

Considerations for resolving disputes

Attorneys and business executives are familiar with litigation as a means of conflict resolution. However, for life sciences companies, outside of very specific circumstances, litigating disputes is generally destructive. It tends to be a protracted and costly endeavor. For example, in the United States, attorney costs in a patent case litigated to first-instance court decisions typically range from $1.5–4 million[3]. Depending on the federal district and whether a jury or bench trial was used, patentee success rates have historically ranged from 33–85%, with a mean time to trial of 2.5 years[4]. Even in 'successful' cases, 80% of district court decisions are appealed and more than half of appeals result in some form of modification to an initial decision. A company's internal costs can be just as draining as external payments to outside counsel, experts, and courts. Managing an expensive commercial litigation may be a substantial burden to an in-house team, tying up thousands of hours of time and other assets, and requiring extensive diligence efforts by company scientists, and depositions or detailed witness statements from company executives.

Even where the legal merits of the case seem to clearly favor one party at the outset of litigation, ultimate success is uncertain, and it is difficult to predict what information may come to light by the time of trial. A 2017 study looked at UK patent litigation from 2000 to 2008 and found that once patent validity is challenged, revocation is the most likely outcome[5]. By contrast, in Germany, only 9.2% of patents are ultimately revoked during infringement suits, but the risks are compounded by needing to initiate litigation before two separate courts in each case. In instances where patents are invalidated by state courts, an international treaty, the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), provides for an opportunity for judicial review of any decision to revoke or forfeit a patent in another country[6]. This further adds to uncertainty, cost, and time.

Patent litigation often needs to be conducted in multiple jurisdictions involving counterclaims of infringement or invalidity that can take years and millions of dollars to litigate, with contradictory advice being given in different jurisdictions[7–10]. Substantive and procedural laws differ greatly between, say, China, which is beginning to eclipse the rest of the world as a jurisdiction for patent litigation, and the United States. Yet even within Europe there is history—dating back to the 1991 *Epilady* litigation—of conflicting decisions from the national courts of European Union member states in relation to the same claims of the same European patent and the same alleged acts of infringement[11]. These conflicting outcomes have occurred despite largely identical substantive patent laws and increasingly harmonized procedural laws[12]. The proposed Unified Patent Court (UPC) is designed to prevent this outcome, but the exclusive jurisdiction of the UPC is limited, there is an 'opt out' provision, and there is a seven-year transitional provision (which may be extended a further seven years). In addition, the UPC still faces some national challenges, and it will not cover the non-EU members of the European Patent Convention[13].

Starting a dispute with litigation can entrench positions and make it less likely that a mutually beneficial settlement can be reached, especially cost-effectively or at a global level. Even winning may be pyrrhic—a respondent may have to file for bankruptcy and be unable to pay adequate damages or a claimant's legal fees, and in some countries, such as the United States, the winning party's legal fees are not usually reimbursed. In addition, life sciences companies may not want to develop a litigious reputation where there is an additional debate about whether access to treatment in public health should trump private sector IP rights[14]. Patent litigation is sometimes fought not only before judges and juries, but in the courts of public opinion and national reimbursement authorities. It therefore befits companies to seek new ways of resolving disputes without litigation. In many instances, we have found that attention to basic interpersonal issues can help to resolve otherwise intractable conflicts, even where millions of dollars may be at stake. **Table 2** shows a checklist for dispute resolution. Checklists are meant to provide a holistic set of considerations for stakeholders in a dispute.

For example, in our hypothetical case above, it may be the case that staff members working for one of the PIs allege that they should have been designated as inventors of an improvement. The precise nature of their contributions may be obscured by a variety of conflicting recollections. Some staff member concerns may have more to do with receiving academic credit than direct financial benefits. It may thus be that, to the extent permitted by patent law, the aggrieved individuals will be content with being named as inventors and assigning their rights without additional consideration. Or, academics can be offered the ability to publish their results in journals as authors, but not be included on certain patent applications. Either way, this must take into account that in some jurisdictions inaccurate naming of inventors can invalidate a patent.

In other circumstances, an understanding of interpersonal issues may not be sufficient. For example, it may be the case that one of the co-owners involved (e.g., a university) is only willing to license its share of a patent jointly owned with a biotech company upon terms that the company believes are unreasonable and not in line with market norms. Different stakeholders may have very different perceptions of market norms. The biotech company may argue to the university that without controlling all of the

rights to a patent it is unlikely any commercial entity will be willing to move forward with the technology.

This sort of impasse may benefit from a structured ADR process. A neutral person participating in discussions could help the parties to identify dispositive issues, find creative solutions that meet the interests of both parties, and appoint neutral parties to work together[15,16]. For example, a neutral might propose that a university receive lower milestone payments in return for higher royalty payments and ongoing grant support to the university for continued research. This may benefit the company, which places a greater present value on its cash, and also benefit the university, which needs ongoing funding for its research. Continued collaboration can benefit both parties in that it may generate new related technologies for commercialization.

Appropriate dispute resolution

Appropriate (or alternative) dispute resolution (ADR) most commonly involves mediation, conciliation, and arbitration or a combination thereof. Mediation tends to be facilitative and non-evaluative (unless specifically requested by the parties, the mediator does not offer his or her own views), while conciliation is normally a more evaluative process in which a neutral party helps to resolve certain dispositive facts or principles of law, and proposes possible settlement solutions in a non-binding manner. Arbitration involves an impartial third party deciding a dispute in a binding fashion.

ADR can be combined and tailored to the needs of parties, and runs the gamut from non-evaluative and non-directive (involved parties, rather than the neutral party, decide on their own procedural options and preferences), to evaluative and directive[17]. With arbitration, parties can customize proceedings, for instance, with regards to case deadlines, discovery limits, and confidentiality. A process facilitator can also be used to help identify when to use evaluative (expert determination) and non-evaluative experts for resolving particular issues[18,19]. Modern ADR includes mediation combined with arbitration, minitrials, advisory opinions, and summary trials with decisions in both public (court-annexed) and private settings[20]. Optimally, decision makers should consider their objectives for ADR and consult with experts to determine how these objectives can best be obtained.

ADR may even effectively resolve disputes between parties without a preexisting contractual relationship. For example, in a case where two biotech companies accuse one another of patent infringement, it may be in the best interests of both companies to avoid litigation. Both parties may be able to benefit from cross-licensing one another's technologies, whereas obtaining revocation of a patent publicly in litigation may serve to open the door to competitors.

Advantages and disadvantages of ADR

ADR is becoming more popular as its benefits are recognized. The American Arbitration Association (AAA) has reported that in 2015, 8,360 new business-to-business arbitrations were filed[21]. Of these, 56% were resolved before award, and 44% were resolved early enough that they incurred no arbitrator compensation. By comparison, in 2015, a total of 25,024 private contract disputes were filed in all US federal courts. The International Chamber of Commerce (ICC) has reported that a record 966 new cases were filed for ICC administration in 2016. These cases involved 3,099 parties from 137 countries[22]. Legislation has even been adopted in some countries (e.g., Portugal) to mandate arbitration for pharmaceutical IP disputes[23]. Yet even with the trend toward increased utilization of ADR, a recent international report suggests that there are significant gaps between what stakeholders want and are being offered when it comes to resolving commercial disputes, and that users prefer efficiency, cooperation, and greater use of ADR[24].

ADR has several benefits over litigation. First, ADR tends to be faster than litigation. Second, ADR proceedings are generally confidential. This has the benefit of keeping disputes private, which is often to the reputational benefit of both parties, preventing inadvertent disclosure of trade secret information. Third, ADR can lead to a broader range of outcomes, based on subjective interests rather than legal norms. This can enable business-oriented outcomes that look to the parties' future needs and interests, rather than positions taken regarding past facts and applicable laws, leading to higher satisfaction and compliance by the parties with the outcome.

Fourth, ADR tends to be much less expensive than litigation, at least for complex commercial disputes. Mediation tends to cost from <1% to 4% of the value of a dispute, whereas for arbitration and litigation the costs are considerably higher (from 5% to 27% for arbitration or litigation)[25]. Mixing ADR modes allows fewer evidentiary skirmishes as well as less discovery, less delay, and less motion practice versus conventional litigation or arbitration on its own.

Fifth, the parties to ADR have the opportunity to select mediators and arbitrators (or combinations of different neutrals) with relevant expertise in different aspects of life sciences disputes. They may bring together neutral persons who understand the science, relevant law, finance, and industry practices. Judges may have difficulties adjudicating technical challenges, which require a high level of scientific expertise or determining the value or quantum of various claims. This is a particular concern in the life sciences where contracts may be unusually complex, or compensation schemes elaborate. For instance, the World Intellectual Property Organization (WIPO), JAMS, and the International Centre for Dispute Resolution (ICDR) have panels of arbitrators with specific IP and life sciences expertise.

Sixth, even when these proceedings were ordered by the courts, most mediated cases settle, even when ordered by the courts rather than required by the parties. For instance, WIPO reports that WIPO-based mediation has a settlement rate of 70% and an arbitration settlement rate of 40% (ref. 26). Combining the two thus provides a likelihood of settlement that is greater than 80% (ref. 27).

Seventh, ADR may help to preserve commercial relationships to a greater extent than litigation, which may be public and contentious. Even in 'business divorce' cases, ADR often permits parties to continue to work together, which is necessary in life sciences, where companies are often merging and entering into new strategic alliances.

Finally, ADR may have particular benefits in the context of international disputes, where the parties wish to select a single, neutral jurisdiction to resolve all issues and reduce some of the national or regional risks using a selected group of international experts as arbitrators, or to work as a dispute resolution board. With regard to international disputes, it may be easier to enforce consent awards reached using arbitration and mediation than court awards, as most nations are party to the New York Convention[28], which allows the enforcement and mutual recognition of arbitration judgments. For this reason, arbitration is often a preferred way of adjudicating international commercial disputes, although in the IP field validity is not arbitrable subject matter in some jurisdictions[29]. Arbitrator awards are generally final and binding on the parties, subject to very limited judicial review for claims such as fraud, denial of due process, or a tribunal exceeding its jurisdiction[30].

Not all disputes are appropriate for ADR, however[31]. ADR usually requires either that the parties to a dispute both agree to ADR, or that they have a preexisting contractual obligation to pursue ADR. Therefore, it may not be possible to require, for instance, an alleged third-party patent infringer to agree to mediation or arbitration. ADR may not be well suited for dealing with patent-infringing

counterfeit goods, where law enforcement may be needed, and where broader and faster measures may be available from customs or administrative tribunals. In addition, for measures such as preliminary injunctions, freezing of bank accounts, and preservation of goods, while most rules give arbitration tribunals such jurisdiction, ultimately parties may need to go to a national court for enforcement.

Finally, in some instances litigation can be used strategically. For instance, a large and well-resourced company may benefit from prolonged and costly litigation with a smaller disruptor. Or, a large IP holder may want public proceedings to get clear jurisprudence or binding precedents related to enforcing its IP rights. Parties may engage in litigation as a negotiating tactic to apply leverage and derive strategic advantage. In such instances, one party may not agree to opt for ADR.

Conclusions

Litigation is usually an unsatisfactory means for resolving disputes for fast-moving technologies, or in converging technical domains such as in the life sciences, where there is a greater need for big data and bioinformatics. Long gone are the days when 'deep pocket' patentees were prepared to slog out the same case in multiple jurisdictions[32]. Today, businesses seek efficiency before certainty of outcome, at a reasonable cost and as expeditiously as possible[25]. In this respect, a holistic approach to process design and the choice architecture of conflict-solving using the most appropriate forms of dispute resolution can be invaluable. This can help stakeholders to keep their focus on patients and innovation.

COMPETING INTERESTS

The authors are all panelists on the World Intellectual Property Organization's List of Mediators and Arbitrators, in addition to other national and international dispute resolution services providers, specializing in intellectual property and technology-based disputes.

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