

TABLE OF CONTENTS

I. INTRODUCTION ..... 3

    A. Biotech Commercial Disputes ..... 3

    B. Challenges of the Current Legal System ..... 4

    C. Goal of the ODR System ..... 5

II. AN ODR SYSTEM FOR RESOLVING BIOTECH COMMERCIAL DISPUTES ..... 6

    A. Platform..... 6

    B. The Agreement to Dispute Resolution..... 6

    C. Starting the Resolution Process ..... 7

    D. Appointment of the Mediator..... 8

    E. Mediation in a Virtual Conference Room..... 9

    F. Escalation..... 10

III. EVALUATION OF THE ODR SYSTEM ..... 11

    A. Key Performance Metrics (KPIs)..... 11

    B. Advantages of the ODR System ..... 12

    C. Potential Issues and Solutions..... 12

IV. FUTURE OF THE ODR SYSTEM IN RESOLVING BIOTECH BUSINESS  
DISPUTES ..... 13

Appendix 1 ..... 15

Appendix 2 ..... 16

Appendix 3 ..... 17

## I. INTRODUCTION

### A. Biotech Commercial Disputes

Biotechnology has been widely regarded as one of the most promising frontier technologies for the coming decades.<sup>1</sup> The United Nations Convention on Biological Diversity defines “biotechnology” as any technological application that “uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.”<sup>2</sup> The business of biotechnology is highly complex, spanning across numerous fields including medicine and health (*e.g.*, pharmaceutical products, medical devices, and surgical and radiological processes), agriculture industry, and environmental science.<sup>3</sup>

Companies conducting business in biotechnology (or biotech companies) often contract with one other. For instance, biotech companies often contract to acquire, sell, or finance other biotech business or research projects; manufacture, distribute or deliver biotech products; provide research & development (“R&D”) services; or license intellectual property rights. The biotechnology market was valued approximately USD 216.5 billion in 2011, and was estimated to reach a value worth USD 414.5 billion by the end of 2017.<sup>4</sup>

As in any other business sector, disputes often arise in biotech transactions. Such disputes share several common characteristics. For instance, they involve highly complex underlying science/technology, as well as proprietary/confidential information, such as trade secrets, from which the biotech companies derive significant economic value.<sup>5,6</sup> Because biotech

---

<sup>1</sup> European Commission, *Life Sciences and Biotechnology – A Strategy for Europe* (2002).

<sup>2</sup> U.N. Convention on Biological Diversity, art. 2, at [www.cbd.int/convention/articles.shtml?a=cbd-02](http://www.cbd.int/convention/articles.shtml?a=cbd-02).

<sup>3</sup> *See, e.g.*, Judy Arbique, *Biotechnology – Science and Engineering Work Together 1* (2006).

<sup>4</sup> *See, e.g.*, *Global Biotechnology Market by Application (Biopharmacy, Bioservices, Bioagri, Bioindustrial), by Technology (Fermentation, Tissue Regeneration, PCR, Nanobiotechnology, DNA Sequencing & Others) - Industry Analysis, Size, Share, Growth, Trends and Forecast, 2010 – 2017*.

<sup>5</sup> *See, e.g.*, Yali Friedman, *A Global Biotechnology Survey*, *Worldview Scorecard 3-4* (Scientific American WorldVIEW 2010).

business transactions are often international in nature, they often give rise to cross-border disputes amongst parties from different regions or nations of the world. Furthermore, biotech disputes often arise in a fast-paced, highly competitively commercial market, demanding prompt and efficient resolution.<sup>7</sup> In light of the above characteristics, court litigations often are not best suited to resolve biotech commercial disputes.

## B. Challenges of the Current Legal System

Biotech companies often resort to court litigation to resolve their disputes. However, as Jon Newman noted:

Whether we have too many cases or too few, or even, miraculously, precisely the right number, there can be little doubt that the system is not working very well. Too many cases take too much time to be resolved and impose too much cost upon litigants and taxpayers alike.<sup>8</sup>

Litigation is probably not the most suited in resolving biotech disputes. In court litigations, trial judges are often randomly selected and assigned to cases. Although a judge is typically highly intelligent, he/she may have little or no experience in the underlying science/technology, the type of biotech transaction, or the laws and government regulations associated with the dispute. The lack of an expert decision-maker in court litigation is one of the reasons why the current court system may not be the most suited to resolve complex technical or scientific disputes. Moreover, it is well-recognized that “[p]layers in fast-paced technology markets cannot afford to have progress stalled for lengthy and expensive litigation.”<sup>9</sup> Biotech businesses can be severely disrupted or even disabled by the uncertainties and negative publicities associated with lengthy and expensive legal battles, especially in view of the pressure to outcompete the potential

---

<sup>6</sup> See, e.g., John F. Hornick, *Trade Secrets: What Your Company Needs to Know*, IP Litigator 1 (2004).

<sup>7</sup> See, e.g., Yali Friedman, *A Global Biotechnology Survey*, Worldview Scorecard 3-4 (Scientific American WorldVIEW 2010).

<sup>8</sup> Jon Newman, *Rethinking Fairness: Perspectives on the Litigation Process*, 94 Yale L.J. 1643, 4644-45 (1985).

<sup>9</sup> Sandra J. Franklin, *Arbitrating Technology Cases – Why Arbitration May be More Effective than Litigation When Dealing with Technology Issues*, Mich. Bar J. 31, 32 (2001).

competitors in the fast-growing market. Finally, preserving confidentiality of proprietary business information such as highly valuable trade secrets is critical for biotech companies. Non-disclosure agreements (“NDAs”) are often used in biotech business transactions. However, keeping confidentiality of sensitive information is problematic during litigations. For instance, in the United States and some other countries, judicial proceedings are often open to the public. Therefore, anyone may gain access to information or documents involved in court proceedings.

In recent years, some biotech companies have turned to mediation and arbitration in resolving their commercial disputes. Mediation and arbitration are forms of alternative dispute resolution (“ADR”) that has existed for a long time.<sup>10</sup> Many believe that such ADRs are more suitable forms of dispute resolution approach for high-tech businesses.<sup>11</sup> They often involve a process allowing the parties to resolve their differences in the private. They are faster processes with assistance from a qualified expert mediator or arbitrator who has knowledge of the underlying science/technology, the type of biotech transaction, and the “customs” in the trade. Online dispute resolution (“ODR”) is the use of technology to improve the efficiency and access to ADR.<sup>12</sup> It combines the benefits of ADR and information technologies to build a more efficient and flexible system of dispute resolution.

### C. Goal of the ODR System

This paper will provide an ODR system that implements information technology in assisting biotech commercial dispute resolution processes. In particular, this paper describes an ODR system that emulates and provides the characteristics of a conventional face-to-face

---

<sup>10</sup> See, e.g., Carrie Menkel-Meadow, *Mediation, Arbitration, and Alternative Dispute Resolution (ADR)*, International Encyclopedia of the Social and Behavioral Sciences, Elsevier Ltd. 2015 (2015).

<sup>11</sup> See, e.g., Bender, Jr, Raymond G., *Arbitration - An Ideal Way to Resolve High-Tech Industry Disputes*, Disp. Resol. J. 65, 44-52 (2010).

<sup>12</sup> Colin Rule, *Online Dispute Resolution for Business*, Jossey-Bass (2002).

mediation or arbitration conference between the parties in dispute using an internet connection, personal computers, a videoconferencing program, an automated expert third-party neutral selection process, and a case management system, which can be used with ease by biotech companies and their legal representatives.

## II. AN ODR SYSTEM FOR RESOLVING BIOTECH COMMERCIAL DISPUTES

The ODR system of this paper consists of several main components. Appendices 1-3 set forth schematic illustrations of the system, including the ODR backend database (Appendix 1), story boards representing simplified ODR user-flow for the case submission and resolution process (Appendix 2), and the architecture of the technical systems in the ODR system (Appendix 3). A typical dispute resolution process using the present ODR system involves a number of key stages, including an on-line mediation procedure beginning with an automated expert mediator selection process. These key stages are discussed in detail below.

### A. Platform

Given that most of the biotech transactions are international in nature, the present ODR system should provide a global resolution process that has a single global database powering the overall system (Appendix 1). A website-hosted system would be suitable. For the purposes of this design, we are going to name the website biotechresolutions.org (a fictional website).

### B. The Agreement to Dispute Resolution

As a starting point, parties in a dispute must first reach an agreement to submit their dispute to the ODR proceedings at biotechresolutions.org. There are several ways to achieve the agreement. For instance, the agreement can be included in a contract governing the business transaction between the parties, in which the parties agree that any disputes that may arise under

the terms of the contract shall be submitted to the ODR process at [biotechresolutions.org](http://biotechresolutions.org). Alternatively, the agreement can be drawn up in connection to a specific dispute after its occurrence. Such an agreement can be reached before or after one of the parties (*e.g.*, the complainant) submits a Request for Resolution to the [biotechresolutions.org](http://biotechresolutions.org) website.

By agreeing to submit the dispute to at [biotechresolutions.org](http://biotechresolutions.org), the parties are agreeing to a set of terms that govern the ODR process, including the third party neutral selection, the mediation procedure, assurances regarding the confidentiality of the process and the disclosures made during the process, escalation provisions, and how the costs will be borne by the parties, etc.

### C. Starting the Resolution Process

The dispute resolution process begins when one party (“the complainant”) of the dispute visits the [biotechresolutions.org](http://biotechresolutions.org) website and submits a Request for Resolution to the case management center (the “CMC”) internal at [biotechresolutions.org](http://biotechresolutions.org). The CMC should be an automated case management system that tracks and stores all the information and records of the cases filed with [biotechresolutions.org](http://biotechresolutions.org). The complainant’s Request should set out summary details with regards to the dispute, including information such as (1) the names and communication references of the parties and their legal representatives; (2) a brief description of the dispute; (3) the type of transaction involved; (4) the underlying science/technology; and preferably, (5) a copy of the parties’ agreement to resolution via [biotechresolutions.org](http://biotechresolutions.org). If at the time the Request is submitted, an agreement to use [biotechresolutions.org](http://biotechresolutions.org) has not yet been reached, the complainant will have the option to either obtain the agreement on its own, or ask the CMC at [biotechresolutions.org](http://biotechresolutions.org) to reach out to the other party in obtaining the agreement. These summary details (including the agreement) would be helpful in assisting the CMC to set

up the subsequent resolution procedures. Such information, however, is not intended to limit the scope of the case or possible arguments the party may rely on later.

Once the initial step is completed and an agreement between the parties in dispute has been reached, the CMC will automatically set up the case by assigning a case number, followed by sending an e-mail to the complainant and the other party of the dispute notifying them of the new case and asking them to log into the CMC for more details. All the parties involved will not only have access to information already submitted on their case, but also be able to submit additional information and/or documentation regarding the transaction and the dispute.

#### D. Appointment of the Mediator

The next phase of the ODR involves an online mediation process. This mediation process will take place online on a secure and confidential platform, designed for asynchronous dialogue. Mediation is an informal process in which a neutral third party, the mediator, assists the parties in dispute in reaching a settlement or resolution of the dispute. In recent years, mediation has become an attractive alternative to litigation where parties in dispute wish to minimize the cost-exposure entailed in resolving the dispute, to maintain control over the dispute resolution process, to resolve the dispute in a timely manner, to maintain confidentiality concerning the dispute, or to preserve the ongoing business relationship between the parties.

Because of the high-tech nature of the disputes that biotechresolutions.org aims to resolve, it is critical that the mediator assigned to each case has the requisite technological and/or biotech business background such that he or she can assist the parties in a competent and efficient manner. To that end, biotechresolutions.org provides an automated mediator selection process (AMS). AMS can be accessed from the CMC at biotechresolutions.org.

Based on the summary details submitted by the parties, including information such as a brief description of the business nature and technology field involved in the dispute, AMS will search its built-in directory of informative mediator profiles for the best suited mediator(s) for each case. Each informative mediator profile contains information of a mediator such as his (or hers) technical and legal background/expertise, language proficiency (*e.g.*, fluency in English and Chinese), past mediation experiences (*e.g.*, short summary of the mediator's previous experience and exemplary mediation cases), personal video remarks, and/or former client comments. To provide ideal search results, AMS will use a Machine Learning system trained using historical performance ratings and the mediator and case profiles. At the end of the search, AMS will generate a list of top mediator profiles for the dispute at issue. AMS will then send e-mails directly to the parties' inboxes with the mediator profiles. For instance, AMS can send one mediator profile each time to the parties for approval. The parties can accept or pass on the suggested mediator. If the parties decide to pass on the first suggestion, AMS will send a second profile, and so on. As an alternative, parties can search the directory and suggest their own mediator if they reach an agreement to do so. Once the parties agree on the mediator selection, the case will move to the next phase.

E. Mediation in a Virtual Conference Room

In the next stage, the selected mediator will first conduct an initial telephone conference with the parties (and/or their legal representatives), in which he or she will schedule the mediation timing, finalize the mediation format (*e.g.*, as a videoconference mediation) and procedure, and discuss with the parties the terms of confidentiality applicable to the documents and information disclosed during the mediation proceeding. Following the initial telephone conference, parties will be given 4 to 6 week to prepare for the mediation and to upload further

information and documentation in support of their case to the CMC for the mediator's consideration.

Next, the mediator will log into the built-in videoconferencing program at biotechresolutions.org and set up a virtual conference room for the scheduled mediation. The parties will be provided login information to the virtual conference room prior to the videoconference mediation. Depending on the issues involved in the dispute, the complexity of the technology and business issues, as well as the economic importance of the dispute, the videoconference mediation may involve meetings held on a single day, across several days or over a longer period of time. The videoconference meeting will be held in both joint sessions and several brief caucuses. Furthermore, throughout the process of the videoconference mediation, each party may also undertake, at various stages, private consultations with its advisors and experts to discuss various issues and to evaluate their options.

At the end of the mediation process, if the parties reach a resolution, they will, with the assistance of the mediator, draft and sign a settlement agreement covering all of the outstanding issues in the dispute. The case will then close.

#### F. Escalation

However, not all mediations result in a settlement. If a resolution cannot be reached or if there are any unresolved issues after the mediation process has concluded, the parties will then have the option to seek resolution by binding arbitration, expert determination, or court litigation, as specified in the parties' initial dispute resolution agreement. Arbitration is typically a binding procedure, in which the dispute is submitted to one or more arbitrators who make a final decision on the dispute. In recent years, arbitration has become more popular for high-tech dispute resolutions. There are a number of arbitration institutions that handle biotech dispute resolution,

such as International Chamber of Commerce (ICC), The London Court of International Arbitration (LCIA), The International Centre for Dispute Resolution (ICDR, which is the international arm of the American Arbitration Association (AAA)), China International Economic and Trade Arbitration Commission (CIETAC), International Centre for Settlement of Investment Disputes (ICSID), World Intellectual Property Organization (WIPO), and under a variety of systems of ad-hoc law including UNCITRAL. The parties may choose to escalate the case to a binding arbitration administered by any one of the above arbitration institutions, pursuant to their agreement.

### III. EVALUATION OF THE ODR SYSTEM

#### A. Key Performance Metrics (KPIs)

It is important to engage in rigorous evaluation of the ODR system's use and benefits to ensure both quality ODR service and to gather information to sustain, and more importantly, improve the system. In a successful case, customer satisfaction with the online process and the outcomes may be indicators in evaluating the present ODR system. However, customer satisfaction alone might not be enough. System effectiveness should also be considered as a performance metrics. Effectiveness can be evaluated by examining, for example, the number of cases going beyond the mediation/arbitration steps (*i.e.*, whether the ODR process lead to more or less litigations); rate of compliance with settlement agreements (*i.e.*, whether the ODR process ensures enforceability of the outcome), rate of dispute recurrence (*i.e.*, whether the use of the ODR process lead to higher or lower levels of dispute recurrences among the same parties); and customer loyalty (*i.e.*, whether former customers return to the ODR system with other business disputes that need to be resolved). Other metrics such as time savings, cost avoidances, and improved relationships should also be taken into consideration.

B. Advantages of the ODR System

The present ODR system at biotechresolutions.org has a number of advantages. First, its AMS process selects and provides expert mediators with the requisite technology and legal background that are best suited for each case. Mediators selected by this automated process will have the knowledge of the “customs” or “usages” in the biotech trade, the expertise in the science and technology involved, and will be familiar with the applicable legal and regulatory framework, all of which should prove invaluable in assisting the parties to see the other’s perspectives and resolve their differences. Second, because parties will have to agree to the confidentiality provisions that provide assurances of the confidentiality of the process and the disclosures made during the proceedings, the present ODR system will better preserve the confidentiality of trade secrets and other valuable business information of the participating entities. Furthermore, the ODR process helps parties involved in international disputes save costs by providing online assistance, such as e-mails and virtual conference rooms.

C. Potential Issues and Solutions

For biotech companies, maintaining confidentiality is of the utmost importance during dispute resolution proceedings. It is, therefore, critical for the present ODR system to take all necessary measures to preserve confidential information involved in the ODR process. As set forth above, parties in the dispute must first agree to submit their dispute to biotechresolutions.org by signing an agreement including detailed provisions directed at preserving confidentiality in relation to the existent and outcome of the mediation, as well as all the disclosures made and documentation presented during the process. The parties can further include, as they agree, additional confidentiality provisions regarding subject matter that is of special interest to them.

The mediation process must take place online on a secure and confidential platform, designed for asynchronous dialogue. The ODR website access and system design will follow industry best practices including SSL using HTTPS, multi-factor authentication, limited access, and content storage encryption. The mediator must also enjoy the confidence of both parties, and during mediation process, find a way to enable the parties to gain the other party's perspectives, without disclosing confidential information. Although this may be a difficult task, the AMS process as described above, which takes into consideration the mediator's past experiences and technology/legal background, may be very helpful in matching the most suited mediator to the task.

For a successful ODR system, the outcome must be enforceable. At the end of the online mediation phase, if a settlement is reached, the parties will draft and sign a settlement agreement covering all of the pending issues in the dispute. This settlement agreement is binding between the parties as a matter of contract law. Additional steps may also be administered to ensure enforceability of the process. For instance, in the parties' initial dispute resolution agreement, a provision may be added requiring the parties to agree that mediation will convert to arbitration where an agreement is reached, and the mediator will render an arbitral award consistent with the settlement agreement. Alternatively, parties to the settlement agreement can include a provision that in case of non-compliance, the parties agree to have an arbitrator appointed to draft an arbitral award according to the terms of the settlement agreement.

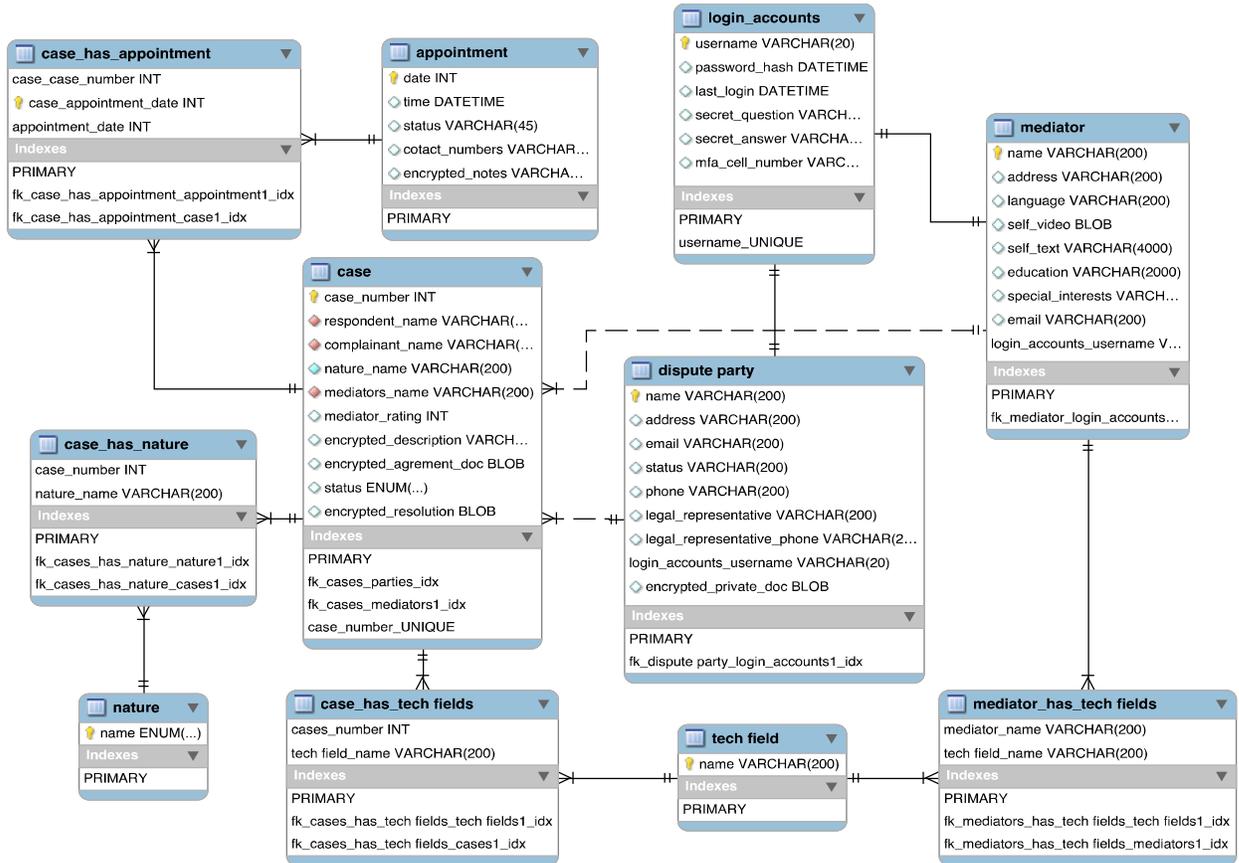
#### IV. FUTURE OF THE ODR SYSTEM IN RESOLVING BIOTECH BUSINESS DISPUTES

Consistent with the current trend for high-tech companies to resort to ADRs in resolving their business disputes, there is a high probability that an ODR system such as the one described herein will be implemented in the near future. There have been a number of institutions that

provide ADR services, such as mediation or arbitration, for biotech commercial disputes. For instance, the WIPO Arbitration and Mediation Center, based in Geneva, Switzerland, offers ADR options for the resolution of international commercial disputes, including some biotech/pharma disputes. Given these institutions' success to date, there is a realistic path to implementing a successful online system for resolving biotech commercial disputes.

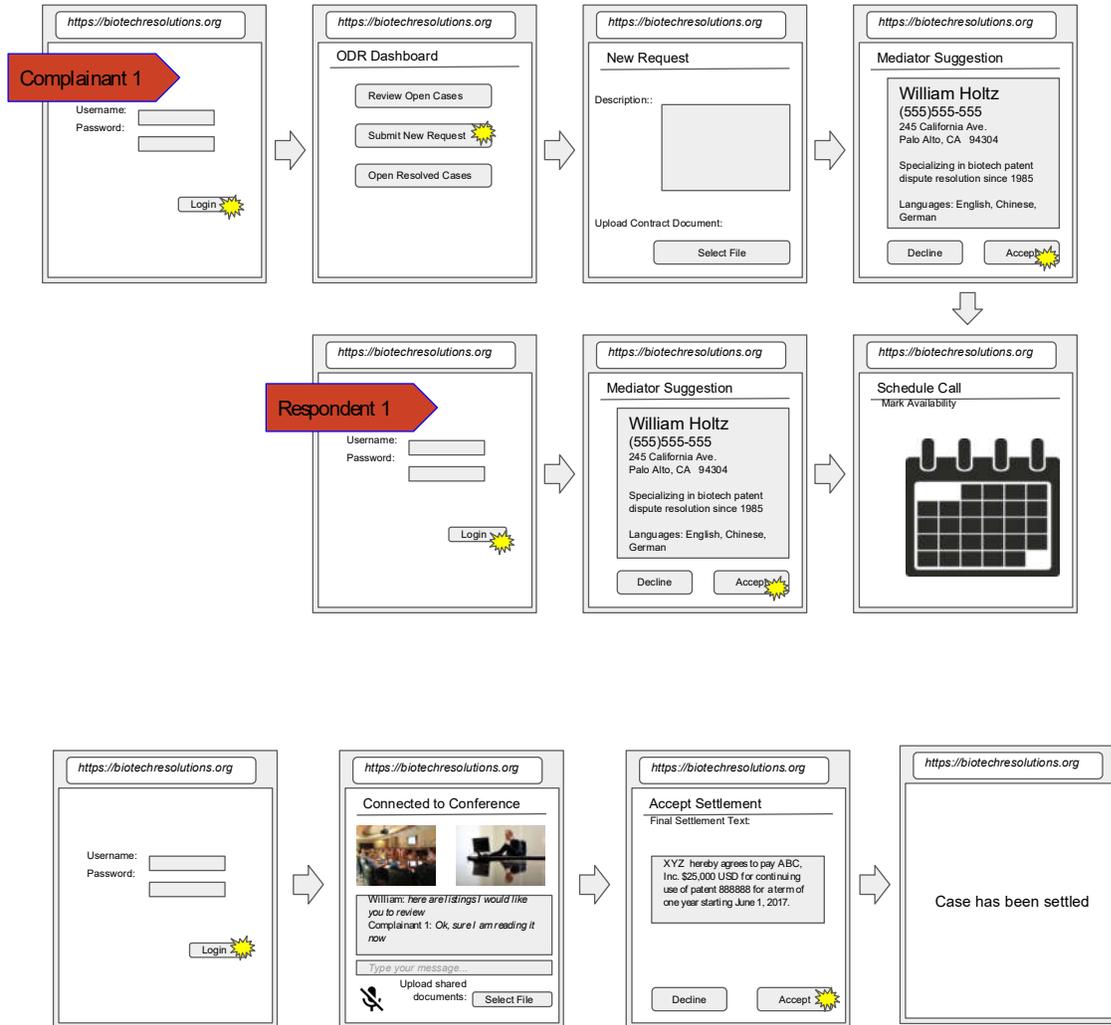
# Appendix 1

## Schema for the ODR backend database



## Appendix 2

Story boards representing simplified user-flow for the case submission and resolution process



## Appendix 3

Architecture of the technical systems in the ODR system.

