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I. INTRODUCTION

We live in an era of technology and innovation. Yet the controversial nature of patents on genes that correlate with human disease has been undisputed since patents were first granted.[1] Scientists have made a lot of progress since the late 1970s. They have developed new strains of plants capable of producing higher yields and resisting viruses, as well as created "transgenic" animals that can produce an array of human pharmaceutical compounds.[2] These compounds would otherwise be unavailable because of the high expense of insufficient sources of supply.[3] Research of genetic materials has also allowed scientists to study the cause of human diseases and target the specific gene sequence that creates the defect.

Patent protection attempts to strike a balance between giving both protection and incentives that lead to inventor creation and the public interest in preventing barriers to the flow of information that might permit invention.[4] Public controversy has centered on the contextual aspects of diagnosing disease through the use of patents that are granted to individuals who discovered disease-associated genes.[5] However, arbitration can be

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1. Robert Cook-Deegan & Annie Niehaus, *After* Myriad*: Genetic Testing in the Wake of Recent Supreme Court Decisions About Gene Patents*, NCBI (Sept. 11, 2014), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4225052/.

2. MARTIN ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW 67 (4th ed. 2015).

3. *Id*.

4. *Id*.

5. Two scholars have noted:

> Policy reports on "gene patents" began to appear in the early mid-1990s, an indicator of emerging policy conflict. The discovery of genetic changes associated with Huntington's diseases, Duchenne[,] and Becker muscular dystrophy, cystic fibrosis, neurofibromatosis, Alzheimer's disease and other conditions led to DNA-based diagnostic methods to identify those at high-inherited risk in families with apparent Mendelian inheritance patterns.

Cook-Deegan & Niehaus, *supra* note 1.

better utilized to solve conflicts with patented inventions. This paper will address the way that gene patents present a special issue in arbitration.

Within the specialized body of law commonly referred to as intellectual property (IP), federal courts are authorized to protect property that fall under the following categories of creations of the mind: inventions, literary works, artistic works, designs, symbols, names, and images used in commerce.[6] The multiple subcategories of IP are protected with laws that govern the legal instruments that are dedicated to each subcategory, which are patents, copyrights, and trademarks.[7] These different instruments facilitate the inventors to earn recognition and wealth from the IP that they create.[8] Therefore, it is easy to see how there needs to be a correct balance between the credit that is due to innovators and also the interest and ability for the public to use the inventions for the public welfare.[9] Thus, the IP system strives to allow innovation and creativity to flourish while also protecting innovator's rights. A specific concern of inventors is the constrained time frame that is desired.[10] If this time frame is elongated unnecessarily, then the proceedings can be harmful to the inventor's rights because technology tends to evolve quickly and can render a pending invention obsolete.[11] These dragged out proceedings can interfere with a business's development plans.[12] For instance, if a company came up with a new product but is unsure of how the patent litigation will be decided, it may be forced to end product production until it is ultimately determined by the court Patent licensing disputes are not typically resolved in arbitration or mediation, but they can serve as preferable methods for resolving the patent process.

License disputes often arise when a patent owner (or licensor) licenses gene patents to a licensee who later disputes that royalties are due because the patent does not cover what the licensee is doing, or because the patent is invalid.[13] Recently, the Patent Office granted a substantial number of patents on genetic sequences that may not be valid pursuant to the 2013 Supreme Court decision in *Association of Molecular Pathology v. Myriad*

6. *What is Intellectual Property?*, WIPO, http://www.wipo.int/about-ip/en/ (last visited Feb. 23, 2016).

7. *Id*.

8. *Id*.

9. *Id*.

10. *See* Craig Metcalf, *Resolution of Patent and Technology Disputes by Arbitration and Mediation: A View from the United States*, 74 ARB: J. CHARTERED INST. ARBS. 385, 385 (2008), http://www.kmclaw.com/media/article/1_metcalf-arbitration%20article.pdf.

11. *Id*.

12. *Id*.

13. *See* D. Brian Kacedon et al., *Licensee May Challenge Patent Validity and Infringement in Royalty Disputes When Royalties are Tied to the Practice of Licensed Patents*, FINNEGAN (May 26, 2015), http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=b27728c0-34d1-4162-9fd0-40298591522e.

Genetics,[14] which held that naturally occurring DNA segments associated with ovarian and breast cancer claimed by Myriad were not patentable under 35 U.S.C. § 101.[15] There, the Court was less than clear when it ruled that isolated DNA in a particular sequence found in nature is not patent-eligible, but that synthetic DNA can be patented because it is not naturally occurring.[16] Thus, patents can be granted to those who invent something new and useful, but not for simple discovery of the location of a gene. However, the Court did not address the patentability of DNA with nucleotides that have been altered.[17] One may wonder if patents can be issued for sequences that have only been slightly altered.

II. SIGNIFICANCE OF THE TOPIC

By 2011, the United States Patent and Trademark Office (USPTO) had issued over 2,500 patents claiming isolated DNA.[18] In addition, the USPTO issued 40,000 patents that were related to human genes existing in forms other than their native form.[19] Patents involving gene sequences will undoubtedly have implications in the future involving different types of genetic testing, agriculture, and gene therapy. For instance, if an artificial gene can be used to treat an illness, and if the artificial gene can be patented, it can prevent competition and make treatment more expensive for members of the public that need it.[20] Furthermore, the person who holds the patent can hold a monopoly over the patented material and licensing fees can often be extremely costly.[21] It can also prevent further research on that specific gene because anyone seeking to use the patented gene would need a

14. Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2120 (2013).

15. *Id*. Section 101 of the Patent Act describes the subject matter that can be patented. 35 U.S.C. § 101 (2015). To be eligible to receive a utility patent, the invention must fall into one of the four categories—processes, machines, manufactures, and compositions of matter—and must also meet the other requirements of the Patent Act. 35 U.S.C. § 101. The Supreme Court has long held that there are certain exceptions to this provision: laws of nature, natural phenomena, and abstract ideas. Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014).

16. *Myriad*, 134 S. Ct. at 2354. In *Myriad*, the Supreme Court affirmed in part and reversed in part the decision of the Unites States Court of Appeals for the Federal Circuit. *Id*. at 2107.

17. *Id*.

18. Charles R. Macedo et al., *Isolated Human Genes and Related Therapeutic Treatment Methods Held Patent-eligible*, 8 J. INTELL. PROP. L. & PRAC. 96, 96 (2013), http://jiplp.oxfordjournals.org/content/8/2/96.abstract.

19. *Id*.

20. *Id*.

21. Sapna Kumar, *Life, Liberty, and the Pursuit of Genetic Information*, 65 ALA. L. REV. 625, 648 (2014).

license.[22] Even with the *Myriad* decision, labs may face issues where cDNA, or synthetic DNA, is patented and they do not hold the patent.[23] Complementary DNA, cDNA,[24] is often used as a starting point for cloning eukaryotic genes, and gene libraries that include only genes transcribed in a particular tissue at a particular time can be made from complementary DNA.[25] Synthesis of cDNA is especially useful for identifying mRNAs that are present only in a few copies.[26]

In some instances, even if they wish to be a licensee, they may not be able to get a license, and if parties go to court, litigation may take years.[27] Especially where health concerns can be pressing i.e. with cancer testing (the *Myriad* decision), two years might make a real difference to a cancer patient seeking to benefit from additional research on diagnostics with the BRCA genes. Arbitration can thus be useful for its shorter time span but also can give the added benefit of utilizing experts who actually have science backgrounds.[28] However, would an increased emphasis on arbitration harm consumers? It may indeed harm consumers because it can keep the specific reasons for the decision unrevealed and confidential.[29] This confidentiality would prevent other parties from quickly learning about the invalid patent and pursuing further research, but those who do arbitrate can be rewarded in the sense that they can reach a faster result and even get a head start on research and development.

Also, reducing the cost of trial might reduce the cost of the patent, since the parties involved in the arbitration dispute may factor in litigation expenses where licensing agreements are involved. Thus, arbitration might be a more efficient and useful solution. As an alternative to arbitration, mediation would be feasibly utilized to diffuse a potentially hostile dispute that could entail a harmful and longwinded litigation. Mediation could transform this type of dispute with a more docile mode of resolution that

22. *See id*.

23. *See* Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013).

24. Complementary DNA is synthesized by combining an mRNA template with a 3' poly A tail with reverse transcriptase enzyme. A short oligo dT primer is added and allowed to hybridize with the poly A tail. Reverse transcriptase synthesizes cDNA using the mRNA template, creating a DNA-RNA hybrid. When synthesis is completed, the mRNA is removed, leaving single-stranded cDNA. DNA polymerase uses the cDNA as a template to make a complementary DNA strand. WILLIAM K. PURVES ET AL., LIFE: THE SCIENCE OF BIOLOGY 326 (7th ed. 2004).

25. *Id*.

26. *Id*.

27. Richard H. Sayler, *The Case for Arbitrating Intellectual Property Licensing Disputes*, 60 DISP. RESOL. J. 62, 62-65 (2005), https://www.adr.org/aaa/ShowPDF?doc=ADRSTG_012013.

28. *Id.*

29. *See* Canon VII of the AAA Code of Ethics (requiring arbitrators to maintain confidentiality). *But see* Laura A. Kaster, *Confidentiality in U.S. Arbitration*, APPROPRIATED DISP. RESOL. (Spring 2012), http://appropriatedisputesolutions.com/site/wp-content/uploads/2013/01/Confidentiality-"DRS-NewsSpr12.pdf".pdf.

meets the goals of both parties and bolsters the product's ability to serve both the creator and the public consumer.[30]

III. BACKGROUND

It is likely true that, without patent protection, "the biotechnology research that lies at the heart of these discovered [patents] might never have occurred."[31] Some researchers also believe that "exclusive licensing of gene patents has reduced the availability of genetic testing to patients."[32] However, due to the landmark Supreme Court decision in *Myriad*, many of the previously granted gene sequence patents are now invalid.[33] When the Supreme Court makes decisions such as *Myriad*,[34] where gene patents are later found to be invalid, the gene patent invalidity issue can significantly impact arbitrations involving gene patent licenses. In such cases, the licensee can argue it is not liable to pay license fees because the gene patent is invalid. If the arbitrator agrees, the licensee does not have to pay the license fee. However, if the arbitration is private,[35] other licensees of the same patent will not necessarily know the result. On the other hand, if a licensee challenges the validity of a gene patent in court, and the court finds the patent to be invalid, this has collateral estoppel impact and releases all licensees from payment of license fees.[36] Collateral estoppel occurs when a judgment in one court action serves as a bar in a later action to the re-litigation of issues that were actually litigated and conclusively adjudicated in the first action.[37]

It would be favorable for a gene patent owner to want a patent dispute to be resolved by alternative means that allow for confidentiality so that other

30. *Dispute Resolution for SMEs*, WIPO ARB. & MEDIATION CTR. 1, http://www.wipo.int/export/sites/www/sme/en/documents/pdf/arbitration_mediation.pdf (last visited Feb. 25, 2015).

31. Jennifer Vogel, *Patenting DNA: Balancing the Need to Incentivize Innovation in Biotechnology with the Need to Make High-Quality Genetic Testing Accessible to Patients*, 61 U. KAN. L. REV. 257, 292-93 (2012).

32. Kumar, *supra* note 21, at 648.

33. Christopher Bergin, *Take Off Your Genes and Let the Doctor Have A Look: Why the* Mayo *and* Myriad *Decisions Have Invalidated Method Claims for Genetic Diagnostic Testing*, 63 AM. U. L. REV. 173, 209 (2013).

34. Ass'n of Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2120 (2013)

35. *See* Canon VII of the AAA Code of Ethics, which requires arbitrators to maintain confidentiality. *But see* Richard C. Reuben, *Confidentiality in Arbitration: Beyond the Myth*, 54 U. KAN. L. REV. 1255, 1256 (2006) (discussing the difference between confidentiality and privacy in arbitration).

36. *See* Blonder-Tongue Labs. v. Univ. of Ill. Found., 402 U.S. 313 (1971).

37. *See Collateral Estoppel*, PRAC. L. (2016), http://us.practicallaw.com/5-518-6335.

licensees are not aware of the outcome. Likewise, the patent challenger often wants to avoid paying the licensing fee, but would also want to prevent the rest of the market from violating the patent because they would not want to draw attention to the fact that it is not a valid patent since, consequently, if other competitors were aware, there would be more competition in the market. Thus, both licensor and licensee may potentially favor arbitration over litigation, and arbitration would likely make both parties to a patent licensing dispute more content with the results instead of resorting to litigation. Arbitration can also occur much more quickly than litigation, allowing research to continue more quickly than if parties waited for an outcome from litigation.[38] This can have a significant impact in the medical field, where human lives are at stake.

Patent disputes resolved through litigation cannot typically be re-litigated, even if a party with an interest at stake was not initially present in the suit.[39] In *Blonder-Tongue v. University of Illinois Foundation*,[40] the Court set forth the rule that once a patent has been declared invalid via judicial inquiry, a collateral estoppel barrier is created against further litigation involving the patent, unless the patentee-plaintiff can demonstrate that they did not have a fair chance to litigate the validity of his patent in an earlier case.[41]

Despite this ruling, in *Lear, Inc. v. Adkins*, the Supreme Court overturned the doctrine of licensee estoppel and held that licensees are free to challenge the validity of a spurious patent under which they are licensed even if a contract entered into among the parties states that he could not challenge it, and thus, the licensee was permitted to refrain from paying patent royalties if the patent he held a license to was deemed invalid, even if the parties had made an agreement not to challenge its validity.[42]

According to the American Arbitration Association, arbitration is a tool that is approved for the resolution for licensing and IP disputes.[43] Specifically, arbitration can resolve disputes involving patents, trademarks, and copyrights.[44] In these types of disputes, arbitration has proven to be more advantageous than litigation in terms of the following categories:

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38. Barbara Kate Repa, *Arbitration Pros and Cons*, NOLO, http://www.nolo.com/legal-encyclopedia/arbitration-pros-cons-29807.html (last visited Feb. 20, 2016).

39. *See* Blonder-Tongue Labs. v. Univ. of Ill. Found., 402 U.S. 313 (1971).

40. *Id*.

41. *Id*.

42. Lear, Inc. v. Adkins, 395 U.S. 653, 675-76 (1969).

43. *Intellectual Property/Licensing*, AM. ARB. ASS'N (2014), https://www.adr.org/aaa/faces/aoe/commercial/intellectualpropertylicensing?_afrLoop=891677053851491&_afrWindowMode=0&_afrWindowId=1bp2y79lfx_203#%40%3F_afrWindowId%3D1bp2y79lfx_203%26_afrLoop%3D891677053851491%26_afrWindowMode%3D0%26_adf.ctrl-state%3D1bp2y79lfx_227 (last visited Feb. 20, 2016).

44. *Id*.

- speed and economy;
- privacy;
- reduced likelihood of damage to ongoing business relationships;
- ease of enforcement in the international context; and
- ability of the parties to customize the process and select arbitrators who are experts familiar with the subject matter of the underlying dispute.[45]

In order to properly facilitate arbitration in the IP law arena, the American Arbitration Association provides panels of neutral arbitrators that have expertise in the following areas of IP: patents, trademarks, copyrights, licensing, technology, biotechnology, and pharmaceuticals.[46] This particularized expertise provides another great advantage over litigation, where judges and jury-members typically have very limited scientific knowledge.

IV. RIGHTS OF AN OWNER

The patent owner is granted the exclusive right to prevent others from making, using, offering for sale, or selling the patented invention.[47] Under 35 U.S.C. § 154 (2015), current statutory provisions, the term of protection for utility patents is twenty years measured from the date of filing[48] with extensions of up to five years permitted for drugs, medical devices, and additives.[49] Also, under 35 U.S.C. § 173 (2015), the current term of protection for design patents is fifteen years from the date of filing.[50] The exhaustion doctrine, which is a longstanding doctrine of patent law, entitles a patentee to a single royalty per patented device and the rule prevents patentees from collecting a series of royalties for a single invention.[51] Thus, the exhaustion doctrine prevents a patentee from bringing an action against a

45. *Id.*
46. *Id.*
47. *See* 35 U.S.C. § 154 (2015).
48. *Id*. § 154(a)(2).
49. *Id*. § 156.
50. *See id*. § 173.
51. Erin Julia Daida Austin, *Reconciling the Patent Exhaustion and Conditional Sale Doctrines in Light of* Quanta Computer v. LG Electronics, 30 CARDOZO L. REV. 2947, 2947-49 (2009).

third party purchaser after having already received a royalty payment from the initial sale.[52]

V. PATENT ARBITRATION

The Patent Act at 35 U.S.C. § 294(a) provides that any arbitration clause contained in a patent agreement shall be presumed valid, irrevocable, and enforceable.[53] Also, the Supreme Court has described the Federal Arbitration Act[54] as evidence of a "national policy favoring arbitration."[55] Even still, as IP attorney Chris Neumeyer explains, the number of disputes in Patent law that undergo arbitration is small.[56] Additionally, internationally, the number is even fewer.[57] In contrast, Neumeyer notes that in 2012 the number of patent-related lawsuits increased to more than 5,000.[58] These 5,000 lawsuits were all filed in U.S. District Courts. Several well-known companies have in recent years resorted to arbitration.[59] The recent trend began in 2012 when both Research in Motion and Nokia successfully underwent arbitration in regards to a licensing dispute.[60] This occurred in a Swedish tribunal that awarded Nokia royalties because RIM infringed standard-essential patents (SEPs) that were owned by Nokia.[61] In 2013 Google proposed that Apple use arbitration to resolve a dispute that concerned particular patents.[62] In this particular dispute, however, the parties did not reach an agreement.[63] In that same year, there was an announcement that Tessera Technologies was owed $130 million in royalties

52. Southland Corp. v. Keating, 465 U.S. 1, 10 (1984); s*ee* Quanta Comput. v. LG Elecs., 553 U.S. 617 (2008).

53. Buckeye Check Cashing v. Cardegna, 546 U.S. 440, 443 (2006); *See* 35 U.S.C. § 294(a) (2012).

54. 9 U.S.C. § 1 (2015).

55. *Southland*, 465 U.S. at 10; Nitro-Lift Techs. v. Howard, 133 S. Ct. 500, 501 (2012) (per curiam).

56. Chris Neumeyer, *Think Patent Arbitration Can't Work? Think Again*, IPWATCHDOG (June 10, 2013), http://www.ipwatchdog.com/2013/06/10/think-patent-arbitration-cant-work-think-again/id=41447/; *see also About Chris Neumeyer*, INT'L TECH. L. BLOG, http://techlaw.biz/author/admin/ (last visited Mar. 3, 2016).

57. *Id*.

58. *Id*.

59. *See id*. (discussing well-known companies such as Google, Apple, and Genetech).

60. *Id*.; Nokia Corp. v. Research in Motion Ltd., 2012 U.S. Dist. LEXIS 174761 (N.D. Cal. Dec. 7, 2012)

61. Neumeyer, *supra* note 56.

62. *Id*.

63. *Id*.

plus $64 million in royalties as per both a patent licensing agreement and an order that had been previously awarded from an earlier arbitration.[64]

By choosing arbitration, parties are able to facilitate savings in multiple ways. Neumeyer notes some of the following methods: to limit the amount of arbitrators, to restrict the scope of discovery, to submit to the pleadings, to prevent the review of a final award, and to impose limits on motions.[65] Also, arbitration can provide for a significant amount of savings in patent disputes that span across multiple jurisdictions by facilitating a single agreement that allows the possibility of halting inter-jurisdictional litigation.[66] Arbitration also allows for flexibility, which is essential because agreement on various logistical issues creates a smoother process. Such logistical issues include: the location for arbitration, the qualifications of arbitrators, access to interim relief, governing law, procedural rules, language, evidence, and timing.[67] Thus, arbitration allows parties to avoid litigation where forums may be biased or where judges or juries are ignorant about essential knowledge of the relevant field. To the contrary, the parties are instilled with the power to select arbitrators who are experts, neutral, and specialized.[68] The International Chamber of Commerce has established a working roster of professional arbitrators that hold the specialized credentials of engineers and patent lawyers.[69]

There are certain situations, however, where arbitration does not provide a resolution to patent disputes across multiple countries.[70] Even still, there are variations in the way different courts reserve the right to arbitrate disputes. In the United States, courts can arbitrate disputes regarding patent infringement.[71] However, that is not the case in China and Japan.[72] If jurisdictions deny the ability for arbitration to govern patent disputes, then it is highly possible that local courts may deny enforcement of awards issued in another country.[73] There are fewer grounds that are used to overturn

64. *Tessera Wins Key Ruling in Arbitration Versus Amkor*, TESSERA (Feb. 20, 2013), http://ir.tessera.com/releasedetail.cfm?ReleaseID=741970.

65. Neumeyer, *supra* note 56.

66. *Id*.

67. *Id*.

68. *Id*.

69. *Id*.; *see also Arbitration and ADR*, INT'L CHAMBER OF COM., http://www.iccwbo.org/advocacy-codes-and-rules/areas-of-work/arbitration-and-adr/ (last visited Apr. 3, 2016).

70. Neumeyer, *supra* note 56.

71. *Id*.

72. *Id*.

73. *Id*.

arbitration awards than there are court judgments.[74] Typically, the main way for arbitration to be upheld is if parties agree to the binding nature of arbitration at any time before the arbitration occurs.[75] Yet many disputes involving patents are not derived from a pre-existing relationship.[76]

VI. GENE PATENTING

The human genome consists of twenty-three pairs of chromosomes within the nucleus of all our cells, with an estimated 30,000 genes comprising the genome.[77] A genome is an organism's makeup of DNA, which contains the complete instructions needed to create and direct the activities of the organism.[78] DNA molecules are large polymers that encode hereditary information that can be passed from generation to generation.[79] By using an RNA intermediate, the information in DNA is used to specify the amino acid sequence of proteins.[80] DNA is made up of four nitrogenous bases that include adenine (A), thymine (T), cytosine (C), and guanine (G).[81] In double-stranded DNA, there is complementary base pairing, where A pairs with T by forming two hydrogen bonds, and C pairs with G by forming three hydrogen bonds.[82] The nucleotide sequence of DNA is copied into ribonucleic acid, or RNA, which is then converted in a linear sequence of amino acids that creates a protein.[83] RNA is a polynucleotide that is different from DNA in that it contains only one strand, a different sugar-ribose instead of deoxyribose, and a fourth base called uracil (U) instead of thymine.[84]

The two steps involving our body's production of proteins include transcription (which copies information of a DNA sequence into RNA) and translation (which converts the RNA sequence into the amino acid sequence of a polypeptide).[85] Messenger RNA (mRNA) travels from the nucleus to

74. *Id*.

75. *See* United Steelworkers v. Warrior & Gulf Navigation Co., 363 U.S. 574, 582 (1960).

76. Neumeyer, *supra* note 56.

77. *Human Genome Project Completion: Frequently Asked Questions*, NAT'L HUM. GENOME RES. INST., http://www.genome.gov/11006943 (last updated Oct. 30, 2010). On April 14, 2003, the National Human Genome Research Institute (NHGRI), the Department of Energy (DOE) and their partners in the International Human Genome Sequencing Consortium announced the successful completion of the Human Genome Project. *Id*.

78. *Id.*

79. PURVES ET AL., *supra* note 24, at 54.

80. *Id.*

81. *Id.*

82. *Id.* at 218.

83. *Id*. at 220.

84. *Id*. at 236.

85. *Id*.

the cytoplasm and serves as a template for the synthesis of proteins.[86] Protein-coding genes contain noncoding base sequences, called introns (that do not code for amino acids) that are interspersed with the coding regions, called exons (that do code for amino acids).[87] There are transcripts of the introns in the primary transcript of RNA (pre-mRNA), but when the mRNA leaves the nucleus of the cell, the introns have been removed and the exons are spliced together.[88]

A much smaller DNA library, that may include only the genes transcribed for a specific tissue, can be made from complementary DNA, or cDNA.[89] cDNA is produced by extracting mRNA from a tissue and then allowing it to hybridize with a molecule called oligo dT (which consists of a string of thymine residues).[90] The oligo dT then serves as a primer, and by using mRNA as a template, is able to synthesize DNA from RNA (making a strand of cDNA that is complementary to the RNA strand, which contains only the exons, as noted above).[91] Complementary DNA is a good starting point for the cloning of eukaryotic genes and is especially useful for cloning genes that are expressed at low levels.[92] If the amino acid sequence of a protein is known, organic chemistry can be applied to create the DNA that codes for the specific protein by figuring out an appropriate base sequence.[93]

If a mutation occurs in a nucleotide sequence, it can result in a harmless alteration, but if it changes the amino acid that is produced, it can cause disease.[94] Because synthetic DNA can be created in any desired sequence, DNA can also be manipulated to create specific mutations, and scientists can then determine how the mutant DNA is expressed in the host cell.[95] Scientists can also extract DNA from cells using lab methods and they are able to isolate segments of DNA (which can be a particular gene, or part of a gene).[96] Genetic testing has led to medical breakthroughs.[97]

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86. *Id*.
87. *Id*. at 285.
88. *Id*.
89. *Id*. at 325.
90. *Id*.
91. *Id*.
92. *Id*.
93. *Id*. at 325-26.
94. *Id*. at 347.
95. *Id*. at 326.
96. *Id*. at 346-48.
97. *Id*. For instance, it was determined that the gene responsible for fragile-X syndrome contains a repeated triplet, CGG, at a certain point in the promoter region. *Id*. at 347. "[E]xpanding

The genetic code is nearly universal, applying to all species on the planet, with the exceptions being "few and slight."[98]

Nine percent of women who inherit one mutated allele of the gene BRCA1 have a 60% chance of having breast cancer by age fifty and an 82% chance of developing it by age seventy.[99] Women who inherit the two normal alleles of the BRCA1 gene are 2-7%.[100]

Myriad found the location of the BRCA1 and BRCA2 genes where mutations in these genes can dramatically increase the risk of breast or ovarian cancer.[101] Before its discovery, scientists did not know which genes were associated with those cancers.[102] By determining the nucleotide sequence, Myriad was able to develop tests that are useful for detecting mutations in these genes and assessing the risk of cancer.[103] Myriad then obtained patents after it discovered the location and sequence.[104] When Myriad determined that a lab at the University of Pennsylvania was using similar testing methods, Myriad sent letters to the university asserting that the testing infringed on their patents.[105] GDL agreed to stop testing.[106] Myriad also filed patent infringement suits against other entities that performed BRCA testing that resulted in settlements in which defendants agreed to cease all allegedly infringing activity.[107] Years later, Ostrer, filed a lawsuit in *Myriad* seeking a declaration that Myriad's patents were invalid under 35 U.S.C. § 101.[108]

Since Myriad found the genes as they occur in nature, the Court, in its precedential decision, found that they are not patent eligible.[109] However, since a lab technician creates something new when cDNA is created, that is a different story and the cDNA is patent eligible.[110] The Supreme Court has left it at that—that genes and the information they encode are not patent eligible simply because they have been isolated from the surrounding genetic material.[111] The Court did not address scenarios such as if a short

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triplet repeats have been found in over a dozen other diseased, such as myotonic dystrophy (involving repeated CTG triplets) and Huntington's disease (in which CAG is repeated)." *Id*.

98. *Id*. at 240.
99. *Id*. at 354.
100. Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2120 (2013).
101. *Id*. at 2112.
102. *Id.*
103. *Id.* at 2112-13
104. *Id*. at 2113.
105. *Id*. at 2114.
106. *Id*.
107. *Id*.
108. *Id*.
109. *Id.* at 2117.
110. *Id*.
111. *Id.* at 2120.

strain of DNA does not have intervening introns to be removed when the cDNA segment is created, which would mean that it would be indistinguishable in form from natural DNA.[112]

Before Myriad's discovery of the BRCA1 and BRCA2 genes, scientists knew that heredity played a role in establishing a woman's risk of developing breast and ovarian cancer, but they did not know which genes were associated with those cancers.[113] Myriad identified the exact location of the BRCA1 and BRCA2 genes on chromosomes 17 and 13.[114] Knowledge of the location of the genes allowed Myriad to determine their nucleotide sequence.[115] That information enabled Myriad to develop tests to detect mutations in these genes.[116] Before this decision was made, Myriad's diagnostic tools were expensive for the average uninsured consumer, costing thousands of dollars (typically around $3,000).[117] After the decision, testing became available by other companies, and the cost of the testing decreased and became more affordable.[118] Although the decision can be looked at as allowing more access to medical tools for the public, it can also be looked at as giving less incentive to companies to develop new testing methods since there appears to be less protection for those who make initial discoveries (and less of a financial reward for these monopolistic companies).

Further, in another recent case, *Ariosa Diagnostics v. Sequenom*, plaintiff Ariosa, formerly known as Aria Diagnostics, sought a declaration that its non-invasive prenatal test, the Harmony test, using cell-free fetal DNA circulating in the blood of a pregnant woman did not directly infringe or contribute to the infringement of U.S. Patent No. 6,258,540 (the 540 patent), that was licensed by the defendant, Sequenom.[119] Sequenom was the exclusive licensee of the 540 patent.[120] The 540 patent related to prenatal detection methods that were "performed on a maternal serum or plasma sample [taken] from a pregnant female," and the methods used detected the presence of a paternally inherited nucleic acid of fetal origin in

112. *Id*. at 2107-20.
113. *Id*. at 2112.
114. *Id*.
115. *Id.*
116. *Id.*
117. Maryn Wilcoxson, Note, *A Lesson Learned from Myriad: The Affordable Care Act As Both an Incentive and an Alternative for Invalidating Stem Cell Patents*, 48 IND. L. REV. 723, 735 (2015).
118. *Id*.
119. Ariosa Diagnostics v. Sequenom, 19 F.Supp. 3d 938, 940-41 (N.D. Cal. 2013) *aff'd*, 788 F.3d 1371 (Fed. Cir. 2015).
120. *Id*. at 941.

the sample.[121] The invention was innovative because it enabled non-invasive prenatal diagnosis, which included sex determination, blood typing, and detection of pre-eclampsia in the mother.[122] Other pre-natal diagnostic DNA tests, such as chorionic villus sampling, utilized invasive procedures that involved risks to the mother and the pregnancy.[123] The noninvasive testing was made possible after the discovery by two doctors that cell-free fatal DNA (cffDNA) is detectable in maternal serum or plasma sample, and that the detection rate was "much higher using the serum or plasma than using the nucleated blood cell DNA extracted from a comparable volume of whole blood."[124]

Ariosa argued that the claims of the '540 patent were not centered on patent eligible subject matter because the patent merely added routine and conventional activity to a natural phenomenon.[125] Yet Sequenom believed that the methods were patentable since they were novel uses of a natural phenomenon.[126] However, in order to have a patent on a process that:

> [F]ocuses upon the use of a natural law, a natural phenomenon, or an abstract idea[,] [the invention] must contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law, natural phenomenon, or abstract idea itself.[127]

The District Court ultimately held that the only inventive concept contained in the patent is the discovery of cffDNA, which is not patentable."[128] Accordingly, the district court granted Ariosa's motion for summary judgment.[129] The court believed that the effect of issuing the patent would be to preempt all know methods of detecting cffDNA at that time.[130] The Federal Circuit later upheld the District Court's decision.[131] According to the Federal Circuit's reasoning, the claims in that case are method claims, which are generally eligible subject matter, yet the court declined to rule that the claim contained an inventive concept that was inventive enough to transform the naturally occurring phenomenon into a

121. *Id.*

122. *Id.*

123. *Id*. at 941.

124. *Id*.

125. *Id*. at 948.

126. *Id*.

127. *Id*. at 948-49 (citing *Prometheus*, 132 S.Ct. at 1294); *see also* Parker v. Flook, 437 U.S. 584, 594 (1978).

128. Ariosa Diagnostics v. Sequenom, Inc., 19 F.Supp. 3d 938, 950-51 (N.D. Cal. 2013) *aff'd*, 788 F.3d 1371 (Fed. Cir. 2015).

129. *Id*. at 954.

130. *Id*. at 949.

131. Ariosa Diagnostics v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015).

patent-eligible invention.[132] The court indicated that "patent claims should not prevent the use of the basic building blocks of technology-abstract ideals, naturally occurring phenomena, and natural laws."[133]

Further, last year the Supreme Court decided another case regarding patents, *Alice Corp. Pty. v. CLS Bank Int'l*, that was centered on patents that disclosed a computer-implemented scheme for mitigating "settlement risk" by using a third-party intermediary.[134] The Supreme Court affirmed the decision of the United States Court of Appeals for the Federal Circuit.[135] Relying heavily on the *Mayo*[136] decision, the court determined that the patents were based on an abstract idea and that "the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention."[137]

VII. CASE LAW - COLLATERAL ESTOPPEL

In *Blonder-Tongue Laboratories v. University of Illinois Foundation*, the Supreme Court held that in patent infringement suits, a patentee (a holder of a patent) is estopped from asserting the validity of a patent that has been declared invalid in a prior suit in federal court against a different defendant, unless the patentee demonstrates that he did not have full and fair opportunity, procedurally, substantively, and evidentially, to litigate the validity of his patent in the prior suit.[138] The case centered on the patentability of antennas.[139] In a prior infringement action, a patent held by

132. *Id*. at 1376. The court noted:

> Because the claims at issue are directed to naturally occurring phenomena, we turn to the second step of *Mayo's* framework. In the second step, we examine the elements of the claim to determine whether the claim contains an inventive concept sufficient to "transform" the claimed naturally occurring phenomenon into a patent-eligible application. We conclude that the practice of the method claims does not result in an inventive concept that transforms the natural phenomenon of cffDNA into a patentable invention.

Id. at 1376-77. *See also* Mayo Collaborative Servs. v. Prometheus Labs., 132 S. Ct. 1289, 1294 (2012); Parker v. Flook, 437 U.S. 584, 591 (1978) ("The process itself, not merely the mathematical algorithm, must be new and useful.").

133. Ariosa Diagnostics v. Sequenom, Inc., 788 F.3d 1371, 1379 (Fed. Cir. 2015).

134. Alice Corp. Pty. v. CLS Bank Int'l, 134 S.Ct. 2347, 2351 (2014).

135. *Id*. at 2360.

136. According to *Mayo*, conventional activity cannot transform an unpatentable law of nature into patent-eligible application of such law. Mayo Collaborative Servs. v. Prometheus Labs., 132 S.Ct. 1289 (2014).

137. *Alice*,134 S.Ct. at 2351.

138. Blonder-Tongue Labs., v. Univ. of Ill. Found., 402 U.S. 313 (1971).

139. *Id*.

the University of Illinois Foundation was determined to be invalid.[140] Thereafter, the Foundation brought an action against Blonder-Tongue Laboratories, the defendant, in the district court for alleged infringement of the same patent.[141] The District Court allowed the Foundation to bring its infringement action against Blonder-Tongue and the Foundation prevailed.[142] The court of appeals affirmed the district court's judgment in favor of the Foundation.[143] Blonder-Tongue then appealed to the United States Supreme Court, arguing that non-mutual collateral estoppel precluded the Foundation from bringing the subsequent action because the patent's invalidity was already established in an earlier action.[144] The court held that once a patent has been declared invalid via judicial inquiry, a collateral estoppel barrier is created against further litigation involving the patent, unless the patentee can establish that he did not have a fair chance to litigate the validity of his patent in an earlier case.[145]

In *Lear, Inc. v. Adkins*, [146] an inventor brought the action against one of the patent's licensees for allegedly breaching the patent licensing agreement.[147] The Supreme Court ruled that there was no estoppel of the licensee in his efforts to assert that the patent was invalid.[148] Furthermore, the Court ruled that the licensee was validly able to decline royalty payments that had accrued if the licensee could prove the invalidity of the patent.[149] The inventor responded by asserting that Lear should be forced to pay the royalties according to the agreement, regardless of the underlying patent's validity.[150] The Court in *Lear* overturned the doctrine of licensee estoppel,[151] holding that public interest considerations require that licensee be free to challenge the validity of possibly spurious patents under which they are licensed.[152] The court held that "the equities of the licensor do not weigh very heavily when they are balanced against the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain."[153] It reasoned that licensees may often be the only individuals with enough economic incentive to challenge

140. *Id*. at 349-50.
141. *Id*. at 314.
142. *Id*. at 314-15.
143. *Id*. at 315.
144. *Id*. at 326.
145. *Id*. at 333.
146. Lear, Inc. v. Adkins, 395 U.S. 653 (1969).
147. *Id*.
148. *Id*.
149. *Id*.
150. *Id*. at 656.
151. *See* Automatic Radio Mfg. Co. v. Hazeltine Research, 339 U.S. 827 (1950).
152. *Lear*, 395 U.S. at 653.
153. *Id.* at 656.

the patentability of an inventor's discovery, and "if they are muzzled, the public may continually be required to pay tribute to would-be monopolists . . . ."[154] The Court addressed that "the technical requirements of contract doctrine must give way [to] the demands of the public interest in the typical situation involving the negotiation of a license after a patent has [been] issued."[155]

In its reasoning, the Supreme Court acknowledged that a conflict exists between the demands of contract law, forbidding a purchaser to "repudiate his promises simply because he later becomes dissatisfied with the bargain," and the policy that requires "all ideas in general circulation be dedicated to the common good unless they are protected by a valid patent."[156] Thus, the conclusion recognizes that the equities of the licensor under contract law were less important than the interests of the public to grant freedom in sharing ideas and promoting competition.[157] Basing its reasoning on the strong federal policy in favor of the free use of ideas, the Court held that the licensee, Lear, must be permitted not to pay patent royalties to Adkins if it could prove that the patent for the gyroscope was invalid, despite the agreement not to challenge the license.[158]

In contrast, typically an arbitration award cannot be used to assert collateral estoppel in a subsequent lawsuit unless there is privity among the parties.[159] Privity requires an identity of interests, or a relationship that is close enough to validate applying the doctrine.[160] In situations where two parties are in privity, the parties must have had their interests adequately represented in order to be bound by such proceeding.[161] Thus, if there is no agreement to the contrary, issues decided by arbitration are able to be re-litigated.[162] For instance, in *Vandenberg v. Superior Court*, the California Supreme Court indicated that it was "compelled to conclude that a private arbitration award, even if judicially confirmed, can have no collateral estoppel effect in favor of third persons . . ."[163] However, there are also

154. *Id*. at 670.
155. *Id*. at 670-71.
156. *Id*. at 668.
157. *Id*. at 670.
158. *Id*. at 674.
159. *See* James M. Westerlind, *The Preclusive Effects of Arbitration Awards*, ARENT FOX (Aug. 20, 2010), http://www.arentfox.com/sites/default/files/Mealeys-Article-PreclusiveEffectofArbAwards.pdf.
160. Citizens for Open Access v. Seadrift Ass'n, 60 Cal. App. 4th 1053, 1070 (1998).
161. Trujillo v. County of Santa Clara, 775 F.2d 1359, 1367 (9th Cir. 1985).
162. *See* Vandenberg v. Superior Court, 21 Cal. 4th 815 (1999).
163. *Id*. at 834.

exceptions. In *Santor v. Superior Court*, the First District Court of Appeals held that since a corporation, a party in the arbitration, could act exclusively through its agents and employees, the findings of the arbitration could be used by third party agents/employees in establishing a basis for collateral estoppel claims.[164] The court held, "[s]ince a corporation may act only through its agents, a finding that the corporation was liable . . . can be pleaded by petitioners as res judicata in the subsequent action against them."[165] The court applied the rules set forth in *Bernard v. Bank of America*, and concluded that the issues decided in the arbitration proceeding with respect to the first, second and third causes of action, were identical with the ones that were pursued in the action against petitioners.[166]

Additionally, in *Kelly v. Vons Cos.*, the court pointed out that issues determined in arbitrations by a tribunal can be given collateral estoppel effect when:

> (1) [T]he issue is identical to that decided in the former proceeding; (2) the issue was actually litigated and (3) necessarily decided; (4) the doctrine is asserted against a party to the former action or one who was in privity with such a party; and (5) the former decision is final and was made on the merits.[167]

The party can be granted collateral estoppel for that issue if the arbitration was not an informal proceeding, but rather contained the formality and safeguards that a formal action may have—the court there determined that the action "had the elements of an adjudicatory procedure."[168] Thus, in addition to the five elements listed above, to rule in favor of applying collateral estoppel, a party needs to also establish that the prior arbitrations had the following elements of an adjudicatory procedure: an impartial officer, a qualified officer, a formal recording of testimony under oath, cross-examinations, motions, discovery, and a written statement of the decision.[169] Consequently, there are exceptions to the rule to not allow the assertion of collateral estoppel by a third party based on a prior arbitration award, but typically collateral estoppel will not apply unless the above listed criteria are met.[170]

On March 20, 2012, the United States Supreme Court ruled in *Mayo Collaborative Services v. Prometheus Laboratories*[171] that a process patent,

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164. Sartor v. Superior Court, 136 Cal. App. 3d 322 (1982); Paloma Ramirez & Patrick Mendes, *The Use of Collateral Estoppel After Arbitration*, TYSON & MENDES (Oct. 16, 2014), http://www.tysonmendes.com/blog-collateral-estoppel/.

165. *Sartor*, 136 Cal. App. 3d at 328.

166. *Id*.

167. Kelly v. Vons Cos., 67 Cal. App. 4th 1329, 1331 (1998).

168. *Id*. at 1336; Ramirez & Mendes, *supra* note 164.

169. Ramirez & Mendes, *supra* note 164.

170. *See* Part VII, *supra*, and accompanying notes.

171. Mayo Collaborative Servs. v. Prometheus Labs., 132 S. Ct. 1289, 1304 (2012).

which Prometheus Laboratories had obtained for correlations between blood test results and patient health in determining an appropriate dosage of a specific medication for the patient, is not eligible for a patent because the correlation is a law of nature.[172] The Court reasoned, "methods for making such determinations were well known in the art, this step simply tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field."[173] The decision has been criticized for conflating two separate patent law concepts (patent eligibility under Section 101 of the Patent Act and obviousness for patentability under Section 103),[174] and potentially invalidating many patents relating to the biotechnology, medical diagnostics and pharmaceutical industries.[175] However, the American Medical Association (AMA) praised the decision for invalidating patents that would have hampered the ability of physicians to provide quality patient care.[176]

VIII. ADDITIONAL DEVELOPMENTS REGARDING PATENT DISPUTES

President Ronald Reagan was responsible for enacting laws, which were to become 35 U.S.C. § 294 in 1983.[177] This section empowered the federal courts' enforcement of arbitration agreements, regardless of the agreement's timing being prior to or following the patent disputes.[178] Furthermore, the Patent Trial and Appeal Board (PTAB) was given credibility as a judicial power over issued patents by the America Invents Act of 2011.[179] The

172. *Id*. at 1297 (noting a process reciting a law of nature is also not considered patentable unless the process has features that "provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself"). *See also* Ariosa Diagnostics v. Sequenom, Inc., 19 F. Supp. 3d 938, 947 (N.D. Cal. 2013).

173. *Mayo*, 132 S. Ct. at 1291.

174. 35 U.S.C. §§ 101, 103 (2015).

175. Gene Quinn, *Killing Industry: The Supreme Court Blows* Mayo v. Prometheus, IPWATCHDOG, (Mar. 20, 2012), http://www.ipwatchdog.com/2012/03/20/supreme-court-mayo-v-prometheus/id=22920/.

176. Charlie Stiernberg, *Supreme Court Diagnotsitc Process Claims as Unpatentable Laws of Nature*, HARV. J. L. & TECH. (Mar. 20, 2012), http://jolt.law.harvard.edu/digest/patent/mayo-collaborative-servs-v-prometheus-labs-inc.

177. *See* Charles W. Shifley, *Goodbye Patent Arbitration?*, BANNERWITCOFF.COM (Fall 2014), http://bannerwitcoff.com/_docs/library/articles/Corporate%20Counsel%20Special%20IP%20Section.Shifley.Goodbye%20Patent%20Arbitration.pdf

178. Charles W. Shifley, *Goodbye Patent Arbitration?*, CORP. COUNS., (Oct.13, 2014), http://www.corpcounsel.com/id=1202672879326/Goodbye-PatentArbitration?slreturn=20150007231928.

179. *Id*.

PTAB does not discern infringement issues.[180] In contrast, the PTAB merely judges the patentability of inventions.[181] However, it cannot judge on claims of patent infringement.[182] Since late 2012, there have been 1,100 petitions filed to the PTAB for the review of patents.[183] Astoundingly, January through June of 2014 saw filings increase to 125% more than the same that were filed in 2013 as a whole.[184] PTAB proceedings benefit the goals of patent challengers because the PTAB has denied patentability to many claims.[185] Due to the recent increase in PTAB proceedings, arbitration may have another need to be revived.

A. The Way Arbitration Works

Typically, when the disputing parties' determination has been made to arbitrate as opposed to litigate, the parties must give notice and agree to the binding nature of arbitration.[186] Furthermore, the resulting award of the arbitration cannot be enforced unless the Director of the Patent Office has been notified and this notice becomes a part of the patent's prosecution record.[187] Notwithstanding the undeniable power of the aforementioned agreements, the Director still maintains the ability to rule upon the nature of invention's patent and what it claims.[188] Thus, the arbitration binds the parties, but "the patentability of the invention goes to the public interest in having only valid patents in existence."[189]

Section 294 of the Patent Act allows for arbitration clauses in of any contractual dispute that relates to patent validity or infringement.[190] This section usually relates to patent license agreements, but can be broader.[191] Parties can agree to arbitrate either in the contract or after the dispute has arisen.[192] If they agree to arbitrate after the dispute has arisen, they may agree to it in writing.[193] Interestingly, Section 294(c) states that the award

180. *Id*.
181. *Id*.
182. *Id*.
183. *Id*.
184. *Id*.
185. *Id*.
186. *See* David Allgeyer, *Arbitrating the Patent Case Part IX: Statutory Provisions*, ADR COMMUNITY (Oct. 28, 2014), https://community.adr.org/docs/DOC-1392.
187. *Id*.
188. *Id*.
189. *Id*.
190. *Id*.; 35 U.S.C. § 294 (2012).
191. Allgeyer, *supra* note 186.
192. *Id*.
193. *Id*.

binds only the parties.[194] This could potentially benefit the person who holds the patent. However, there is a lack of clarity on whether an invalidity finding will bind the patent holder if he later sues another party to bolster attempts to capture royalties. With arbitration, the answer is typically no, it would not.[195] However, this ambiguity stems from the fact that 294(c) addresses that arbitration binds the parties to the dispute.[196] Even though another party will have "notice" once it is recorded, the decision of invalidity is not binding over later disputes.[197] However, a licensor can have a provision in the arbitration clause that the award states what is owed in royalties without giving specific reasons.[198] In that case, a third party would not be able to readily determine the rationale for the award or the invalidity determined. Arbitration is a great alternative due to the fact that when jury trials determine the outcome of a patent case, verdicts may seem to lack a logical basis and jurors and judges may not understand the technology involved or background of significant issues.[199]

B. Mediation

Mediation can also be "especially helpful in patent licensing and infringement cases in which the parties can explore mergers, cross-licensing, royalty rate negotiations, etc."[200] It makes sense to utilize mediation with patent disputes since there can be more winners in the equation.[201] Moreover, the parties agree on an outcome that "can avoid the risk of the judge or jury giving an unreasonable award."[202] It is possible that if a patent dispute is delayed due to litigation, a better product may be on the market after hard earned dollars are spent and the litigation is still stagnant and underway. Time is a crucial factor with patent licensing disputes, especially in fields such as the pharmaceutical industry.[203]

194. *Id.*; 35 U.S.C. § 294(c) (1982).
195. Allgeyer, *supra* note 186.
196. *Id.*; *See* 35 U.S.C. § 294(c) (1982).
197. Allgeyer, *supra* note 186.
198. Sayler, *supra* note 27.
199. Metcalf, *supra* note 10, at 385.
200. *Id* at 386 (citing W. Levenson Dean, *Let's Make a Deal: Negotiating Resolution of Intellectual Property Disputes Through Mandatory Mediation at the Federal Circuit*, 6 JOHN MARSHALL REV. INTELL. PROP. L. 369 (2007)).
201. Metcalf, *supra* note 10, at 386.
202. *Id*.
203. *Id*.

The parties "can control how long the proceedings last and set deadlines to ensure that no time is wasted."[204] Other notable aspects favoring mediation is that it can induce settlement by helping to expedite the negotiations processes earlier.[205] Mediation further protects the parties' confidentiality interests.[206] Mediation uniquely enables the parties in dispute to "customize and fortify confidentiality in order to protect trade secrets and other valuable information."[207] Litigation's counterpart to this flexible confidentiality is a protective order.[208] This type of order is issued in the efforts to protect certain information from other parties.[209] Parties in mediation can make the entirety of the proceedings confidential, including the terms of the settlement, and the communications are typically protected and not admissible into evidence in other proceedings.[210] It is clear that the normal background of patent licensing disputes is a contract. Since the adversarial nature of mediation is not nearly as strong as that of litigation, the business relationship can sometimes be repaired.[211] In cases that relate to technology, the mediators are handpicked for their knowledge and experience of the disputed field of law.[212]

IX. INTERNATIONAL ARBITRATION OF PATENT DISPUTES

Some of arbitration's strong suits are that it calls for shorter proceedings, lower costs, and knowledgeable arbitrators.[213] Arbitration is beneficial to parties in patent disputes as the parties typically choose arbitrators that are experts with special technological or scientific expertise in the required field.[214] Because of this expert knowledge, the arbitrators can more easily understand the nuanced subjects that become the heart of disputes.[215] Furthermore, this type of dispute resolution can help avoid confusion and delays.[216] Additionally, because arbitrators can readily understand the pending issues, expert witnesses may not be needed and money can further be saved.[217] If an arbitrator has a depth of knowledge

204. *Id*.
205. *Id.*
206. *Id*.
207. *Id*.
208. *Id*.
209. *Id*.
210. Dean, *supra* note 200, at 369.
211. Metcalf, *supra* note 10, at 386.
212. *Id*.
213. *Id*. at 388.
214. *Id*.
215. *Id*.
216. *Id*.
217. *Id*.

within the field, he will be more likely to adhere to industry standards and to refrain from excessive punishment.[218] However, with litigation, it may be harder for members of the general public to determine the standards within that field and how far one may have deviated from the norm. Thus, it makes more sense for someone who knows the industry well to determine if one has done wrong to another and what a reasonable award for the discretion would be.[219] Also, a panel of arbitrators with their combined expertise could cover several different relevant areas to the dispute.[220]

Additionally, the Federal Circuit reviews patent claims from the cistrict court under the *de novo* standard of review.[221] This means that, once a patent dispute reaches the Federal Circuit Court, the parties then must retry the case from the beginning.[222] Therefore, not only can litigation exponentially increase costs of dispute resolution, but it can also allow for confidentiality to be lost in its lengthy proceedings.[223]

A. International Concerns

If a patent owner has a patent that is being infringed upon in several countries, it is imperative that the owner brings an enforcement action in all of those countries.[224] However, complications do arise in situations where nations differ on their intellectual property philosophies.[225] For instance, in contrast to the U.S. statute, the European Patent Convention does not explicitly state which inventions are patent eligible, but instead excludes specific categories.[226] Some countries allow patents to protect a broader

218. *Id*.
219. *Id*. at 389.
220. *Id*.
221. *Id*.
222. *Id*. at 390.
223. *Id*.
224. *Id*.
225. *Id*.
226. These categories include: "(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; and (d) presentations of information." Convention on the Grant of European Patents (European Patent Convention), art. 52(2), Oct. 5, 1973 [hereinafter EPC] ("Article 52(4) of the Convention prohibits patent protection for methods of treating the human body, diagnostic methods practiced on humans or animals, and methods for treatment by surgery or therapy."); ADELMAN ET AL., *supra* note 2, at 67, 77-78 ("Many have interpreted the limitation of Article 52(1) by 52(4) to embody a general policy that people using surgical, therapeutic, or diagnostic methods as part of delivering medical treatment should not be encumbered by patent rights."). *See, e.g.*, Franz-Josef Zimmer & Ulrike Langheinrich, *Patentability of*

spectrum of rights, whereas some countries remain narrower in their views.[227] Consolidation several proceedings into a single proceeding is ideal because the multi-national claims can get very complex because they can be subject to the judgment of several jurisdictions.

International arbitration through the World Intellectual Property Organization, also known as WIPO,[228] has added benefits when utilized for international parties.[229] WIPO is a United Nations (UN) agency that oversees treaties involving copyright, patent, and trademark laws and was created in 1967.[230] It has registered international patents and also developed international patent legislation.[231] WIPO is a self-governing body that has drafted rules and created the Arbitration and Mediation Center to provide a center that focuses on IP dispute resolution.[232] This system offers parties an effective alternative to international litigation.[233] With 180 members, it offers a solution when parties shy away from settling these types of disputes in the courts of another country due to concerns over partiality.[234] This offers a somewhat simple solution when juxtaposed with the complexities and messiness that can result in several multi-national litigants that bring suits that are governed by various conflicting laws.[235]

Looking at the way ADR can be implemented reveals how, for instance, experienced arbitrators who have a substantive background in the disputed topics can better serve the parties at dispute than most judges could.[236] In addition, this type of experienced referee decreases expenditures and "improves the quality of the decision" by supporting the decision with the arbitrator's own expertise.[237] IP law's sensitivity to timely dispute resolution is unparalleled across multiple fields of law. Undoubtedly, there may be exceptions to certain patent cases where litigation may be necessary. However, many current issues surrounding patent litigation can be solved by the use of mediation or arbitration. These modes of dispute resolution provide parties with decisions that are better founded and more quickly decided so that the public more readily has access to the wealth of knowledge necessary for rapid technological innovation.

Diagnostic Methods Under the EPC: A New Referral to the Enlarged Board of Appeal by the President of the EPO, 23 BIOTECH L. REP. 402, 405 (2004).

227. *See* EPC, art. 52(2).
228. *WIPO*, ELECTRONIC FRONTIER FOUND. (Feb. 14, 2015), https://www.eff.org/issues/wipo.
229. *See id*.
230. *Id*.; Metcalf, *supra* note 10, at 391.
231. Metcalf, *supra* note 10, at 391.
232. *Id*.
233. WIPO, *supra* note 198.
234. Metcalf, *supra* note 10, at 392.
235. *Id*.
236. *Id*. at 393.
237. *Id*.

X. PROPOSED SOLUTION

There should be an increased use of arbitration in resolving licensing disputes. Patent disputes, specifically those stemming from licensing agreements, should go through arbitration because it enables parties to take advantage of arbitration's tendency to promote confidentiality, specialization, finality, and cost-savings.[238] Arbitration can be a voluntary process where the parties agree to have a neutral third-party. In addition, the disputing parties would ideally choose a highly qualified professional who has knowledge of the nuanced field that gives rise to the dispute.[239] Additionally, the informal process of arbitration offers flexibility, high pace, and a finality that draws from arbitration's binding nature.[240] All of these traits of arbitration support the goals of facilitating business and innovation.[241]

In contrast, litigation entails an inventor filing a complaint and alleging breach of licensing contract or infringement of patent. The defendant would claim that the patents are invalid and therefore, there is no infringement. This process would call for discovery and possible waiting times between motions of past an entire year. The final judgment at trial can be continued and delayed to a point where time has been wasted and both parties grow stale. In addition, the opportunity for an appeal on the final verdict could extend the case even further until the "company's IP rights and product lines have been in legal limbo" for years.[242] If the dispute is resolved according to arbitration rules, "[b]ecause the arbitrator understands patent law, she is able to efficiently review and understand a large volume of testimony and evidence, including complex technical data,"[243] and can do so quickly to potentially get a product more readily available on the market.

Other countries have even considered eliminating human gene patents.[244] Those who oppose gene patenting argue that costs of healthcare would decrease and progress in research would increase.[245] However, those parties who support gene patenting bolster their argument with the idea that the patent system provides the required incentives that support innovations

238. Allgeyer, *supra* note 186, at 10.
239. *Id*.
240. *See* Metcalf, *supra* note 10, at 389.
241. Allgeyer, *supra* note 186, at 10.
242. *Id*.
243. *Id*.
244. Kate M. Mead, *Gene Patents in Australia: A Game Theory Approach*, 22 PAC. RIM. L. & POL'Y J. 751, 771 (2013).
245. *Id*.

within the biotechnology field.[246] Due to their profound impact on human life and disease-prevention, gene patents present an issue that needs modification. The complex processes of licensing and royalties can serve to deter genetic research. Arbitration is a tool that can streamline this process and provide better results.

XI. HOW THIS PROPOSAL COULD IMPACT PUBLIC WELFARE

On November 3, 2014, the Children's Hospital of Eastern Ontario, Canada brought suit against the University of Utah regarding patents held by the university for genes associated with Long QT Syndrome.[247] The syndrome causes abnormal, life-threatening heart rhythms and children that inherit certain genetic mutations die suddenly from the condition unless they receive the necessary genetic testing and therapy.[248] The University of Utah first obtained Long QT gene patents in 1997, and then initially licensed its rights to a U.S. company that did not develop any genetic testing, but did stop other entities from studying the genes, including suing a U.S. laboratory that was offering a Long QT test to the public.[249] Due to gene patent disputes, there was no genetic testing offered for the disorder in the United States for two years.[250] As a result, doctors could not test patients that they believed may have the genetic mutations and, consequently, could not prescribe the effective therapies.[251] A case in point is that of 10-year old Abigail, an American citizen, who succumbed to Long QT Syndrome and died undiagnosed.[252] Notwithstanding *Myriad*'s holding that a naturally occurring genetic code cannot be patented, there are several American universities and companies that have maintained foreign patents on the same genes for which they hold a patent in the United States.[253] PGx Health, an American organization acting with the help of the University of Utah, acquired licensing to Long QT.[254] Through these acquired licenses, PGx halted Canadian medical center's efforts to administer testing to patients.[255] As a result, the cost of the test skyrocketed to an unreasonably high rate of

246. *Id*.

247. Misha Angrist et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Long QT Syndrome*, 12 GENETICS MED. 111, 154 (2010).

248. *Id*.

249. *Id*.

250. *Id*.

251. Sandra S. Park, *The Fight to Take Back Our Genes Moves to Canada*, ACLU (Nov. 6, 2014), https://www.aclu.org/blog/womens-rights/fight-take-back-our-genes-moves-canada.

252. *Id*.

253. *Id*.

254. *Id*.

255. *Id*.

over $4,000 per patient.[256] This cost was a result of international postage rates, and is extremely unreasonable considering that local Canadian hospitals were slated to charge a grand total of $1,500 per tested patient.[257] It is clearly unethical when the corporate concern of increased income generation takes precedence over the international availability of life-saving testing.

A. How Could a System Be Put Into Place?

In her article, Kourtney Baltzer proposes that a clearinghouse could be established for monitoring and enforcement of licensing deals, with a potential alternative dispute resolution system that could include mediation and arbitration.[258] This system would be tailored to the clearinghouse's granted biotech patents.[259] She explains how this would be attractive to patent licensees and patent holders, because of its relative cost-effectiveness and risk-averseness in comparison to litigation.[260] Baltzer further advocates the suggestion by specifying that the clearinghouse's license agreements would maintain a clause requiring that all disputes related to the license must be resolved through the clearinghouse's established ADR methods.[261] This system would ensure that the parties' expectations regarding future dispute resolution are settled on at least the forum and the methodology.[262] This not only streamlines the process but it creates a security blanket for the parties involved, because they know the forum is fair. Systems similar to Baltzer's proposed alternative dispute resolution clearinghouse could have a profound positive consequence on the future of our patents—especially since it would prevent companies from losing years of research to litigation.

B. Discussion of Potential Objections

While it is possible that requiring arbitration and confidentiality in licensing agreements would be harmful to consumers, it is unlikely. One

256. *Id*.
257. *Id*.
258. Kourtney Baltzer, *A Clearinghouse: The Solution to Clearing Up Confusion in Gene Patent Licensing*, 24 HARV. J.L. & TECH. 519, 537 (2011).
259. *Id*.
260. *Id*.
261. *Id*. at 534-35.
262. *Id*. at 535.

problem, however, is that arbitration clauses may be difficult to enforce. If a clearinghouse was utilized to grant licenses, it may pose several problems.

Objections could possibly be focused on arbitration's pitfalls. One of these pitfalls is the limited nature of discovery under the arbitrator's orders.[263] This limitation denies the parties the multitude of evidence that would have otherwise been available to the parties in the pre-trial stages of litigation.[264] With the complexity that sometimes surrounds these disputes, a lack of evidence could prove to be detrimental to a party's claims.[265] Additionally, although parties to arbitration are supposed to be bound by their agreement to arbitrate, there is no definitive answer to the question of how extensively the agreement can be enforced.[266] For example, will the decision be binding in future court proceeding or even those of the USPTO?[267] It is unclear where the results of litigation and the results of arbitration intersect.

XI. CONCLUSION

Patents on genes are ready and able to disrupt innovation and technological advancement, "as innovators may find it daunting to obtain licenses from all of the many different patent holders of genes that can be simultaneously screened."[268] Although *Myriad*[269] made some headway in preventing patents on naturally occurring genetic material, labs may still decide not to develop a test on a disease due to licensing issues with patents, and there is confusion stemming from that precedential decision that seemed to cast blurred lines. The complexities that may arise from the Court's unclear reasoning can decrease a patient's ability to access critical genetic testing. Since litigation can take years, and because there are less hostile ways of solving licensing disputes, a more widely used system of arbitration should be put into place.[270] Even though the future is unclear, it seems that the Supreme Court will allow certain systems of DNA inventions to be patented, though it is not likely to grant any patents for individual genes. [271] Although the innovations addressed in *Myriad* and *Ariosa* made significant

263. *See* Mason, Derek J., *Arbitration: A Quick And Effective Means For Patent Dispute Resolution*, LICENSING EXECUTIVES SOC'Y INT'L., (Dec. 2011), http://www.oblon.com/publications/arbitration-a-quick-and-effective-means-for-patent-dispute-resolution/.

264. *Id.*

265. *Id.*

266. *Id*.

267. *Id*.; *See also* Federal Arbitration Act, 9 U.S.C. §§ 1-14 (2006).

268. Baltzer, *supra* note 258, at 521.

269. Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107 (2013).

270. Cook-Deegan & Niehaus, *supra* note 1.

271. *Id*.

contributions to the medical field, the inventions at stake were still not patentable.[272] The pivotal point of patentability will likely depend on "methods that more clearly reflect the art of inventions rather than the labor of discovery."[273] Perhaps the difficulties with recent Supreme Court decisions such as *Myriad* hint at the fact that lines to be drawn are not so clear. For instance, would one be able to simply make a silent mutation in the cDNA to avoid infringing on a patent?[274] Perhaps cases need to be decided on a case-by-case basis, which seems to fit perfectly with arbitration. Arbitration may prove to allay inventors' fears of subjecting their inventions to the risks of being invalidated, exposed, or negatively publicized.[275] It may also allow the licensee a quicker chance to get their product on the market and available to those in need. Since arbitrations are quicker, more cost-effective, and do not need to reveal specific determinations, it may provide for the sensitivities of each party's needs. This allows for companies to take advantage of arbitration decisions that are in their favor—without the need to disclose the decision to competitors, and the patent holders do not have to face public disclosure of the decisions that were made. Additionally, different companies may alter their invention in a number of ways so that the arbitrators may not reach the same decision based on the differences in their alterations. The affect of arbitration would thereupon allow companies to make different modifications to the product, which would be made possible by the use of arbitration. Also, the arbitrator finds the patent is invalid and the licensee does not have to pay royalties, the licensee would not be concerned with whether or not competitors pay royalties. However, even if competitors do pay royalties, the previous licensee will gain be a competitive advantage.

In conclusion, it is surprising how few arbitrations resolve disputes related to patents.[276] Internationally, the number of patent disputes that are submitted to arbitration are merely below one thousand.[277] With the benefits of arbitration and the hazy Supreme Court decisions that implicate our

272. Ass'n for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2107 (2013); Ariosa Diagnostics v. Sequenom, 19 F. Supp. 3d 938, 938 (N.D. Cal. 2013) *aff'd*, 788 F.3d 1371 (Fed. Cir. 2015).

273. Cook-Deegan & Niehaus, *supra* note 1.

274. *See Current Events: Supreme Court Rules on Gene Patenting*, HOW SCI. IS MADE (June 21, 2013), www.howscienceismade.com/2013/06/gene-patent-supreme-court.html.

275. John Conley, Myriad, *Finally: Supreme Court Surprises by not Surprising*, GENOMICS L. REP. (June 2013), http://www.genomicslawreport.com/index.php/2013/06/18/myriad-finally-supreme-court-surprises-by-not-surprising/.

276. Neumeyer, *supra* note 56.

277. *Id*.

genetic code, it seems to be an excellent means of resolution that should be utilized more in the future. It would be wise for parties to include arbitration agreements in their licensing agreements and would have benefits for both parties. It is hard to predict what the future has in store and which human diseases may be prevented. Although lines need to be more neatly demarcated, and mediation may prove to be a special tool for solving related disputes as they arise, it is clear that science is reaching new highs and technology will meet new bars as it progresses. However, keeping innovation barriers at a minimum[278] is significant for an ever-evolving world where litigation can halt progress and risk the loss of medical treatment and the lives of those in need of care.

278. *See also* ADELMAN ET AL., *supra* note 2, at 67 ("For a time, both the case law and roll of granted patents seemed to suggest that if you could name it, you could claim it within a patent instrument. Accordingly, patents issues for business methods, tax strategies, computer software, and even human genes were among controversial proprietary rights that were issued by the USPTO.").