The Treatment of Know-How in International R&D Cooperation:

The United States of America

F. Scott Kieff*

Professor of Law at Washington University School of Law and Research Fellow at Stanford University's Hoover Institution.

This work is part of the Hoover Project on Commercializing Innovation, which studies the law, economics, and politics of innovation, and which is available on-line at www.innovation.hoover.org. Correspondence may be sent to fskieff.91@alum.mit.edu.

Table of Contents

I. Legal Consciousness and Approach to Legal Thinking

The US national government is a federal government that, by the US Constitution, is a government of limited power, leaving most areas of law in the hands of the country's 50 member states. Areas of law like patent and copyright are questions of federal law, and so are essentially uniform across the country. Areas of law like property, contracts, and trade secrecy are questions of state law, and so these often vary state by state.

At both the federal and state level in the US, the government is generally divided into three branches: legislative, executive, and judicial. At the national level, the legislative branch is divided into the two Houses of Congress: the Senate and the House of Representatives. The citizens of each state elect two Senators to the US Senate and a number of Representatives to the House of Representatives that is a function of the size of the state's population. The leader of the executive branch at the national level is the President, while at the state level the leader is the Governor. Most national government agencies, such as the Patent and Trademark Office, are under the direct control of the executive branch. The Directors of most executive branch agencies at the national level are appointed by the President, confirmed by the Senate, and serve at the pleasure of the President, which means they often are replaced by each new President. At the national level, most judges of the judicial branch are appointed by the President, confirmed by the Senate, and then are protected in their position by lifetime tenure. At the state level, in some states the judges generally are similarly appointed, confirmed, and protected by lifetime tenure; but in others the judges are subject to elections either for selection or retention or both.

The US national and state governments essentially employ a common law system under which statutes promulgated through the cooperation of the legislative and executive branches of government and typically written to be of general applicability are interpreted by the judicial branch of government for application to particular cases through the issuance of opinions that set forth a legal reasoning analysis of the type that can serve as precedent in later cases. It generally is seen as important for courts in the

US to avoid going so far as to make law themselves, as opposed to interpreting the laws made by the cooperation of the other branches of government. It also generally is seen as important for courts in the US to write opinions that explain their reasoning to at least the particular parties of the case being decided, if not also to all potential future parties in similar cases.

Yet, the approach as just described is somewhat idealistic. For example, there are US courts that endeavor to avoid precedential effect of their decisions, such as by obscuring their reasoning. There also are US courts that endeavor to make law, either openly or surreptitiously. Furthermore, while there is a substantial literature studying the political science of decision making by the executive and legislative branches of government that are typically seen as law-makers in the US, which shows how these branches of government can respond to interest group pressure and lobbying, it also has become clear in the US that courts also are not immune from political and social pressures.

II. The Most Relevant Laws for R&D

Overall, there is a great deal of R&D conducted in the US, including by private businesses, by universities, and by government agencies. While the activities that occur in the private sector are or course governed by the body of legal regimes generally known as “private law,” even those activities that are funded with public money are largely also governed by these same laws since the fruits of this work is usually encouraged to enter the private sector through laws like the Bayh-Dole Act, which is discussed later in this report in the section on public intervention. As a result, the most relevant laws for R&D in the US include the private law areas of trade secret, contract, and patent. Both trade secret and contract are matters of state law, and so vary state to state. Patent law is a matter of federal law, and so is generally uniform across the country.

A. Trade Secret

Trade secret law is based largely on theories of tort and contract. The tort principles essentially give rise to remedies for misappropriation of trade secrets. The contract principles essentially facilitate the underlying methods of protection by allowing restrictions on employees and others from using or disclosing the trade secret. However, there are important limitations on the type of contractual limitations that may be used to maintain a trade secret.

Although trade secret law is a matter of state law and therefore could vary state by state, the basics of state law are very similar across states. Generally, any information that is of value and not widely known can be treated as a trade secret. Typical examples include formulas and data. Generally, as long as the party asserting trade secret protection takes reasonable steps to maintain the secrecy of the information, trade secret protection will be recognized by the courts. Typical remedies for misappropriation of a trade secret include damages and an injunction.

1. Obtaining Trade Secret Rights

The range of subject matter that can be protected by trade secret laws is very broad. Almost any type of information used in a business that is not generally known within the industry, and lends a competitive advantage, can be a treated as a trade secret. Concrete technological examples that often come first to mind include formulas, processes, methods, techniques, specifications, tolerances, etc. A great deal about even a product itself may be protected, even when that product is itself made widely available, to the extent that the information sought to be protected is not ascertainable by inspection of the product, reverse engineering, etc. Indeed, so-called virtual black-box licensing often can be used for articles that are leased or licensed for certain uses to protect through contractual prohibitions against disassembling, copying, or reverse engineering what otherwise would be discoverable through reverse engineering.[1] Many

1 Some might view this type of restrictive licensing by a business holding a dominant market position to be limited by the antitrust or anticompetition laws such as § 2 of the Sherman Act in the US or Article 82 in the European Union.

other different types of general business information also may be protected by trade secret laws including lists of customer identifying and contact information, databanks of customer preferences or needs, lists of suppliers, lists of costs or prices, etc.

To be recognized as a legally protectable trade secret, the subject matter must meet four basic criteria: (1) use; (2) in a trade or business; (3) in secret; and (4) be not generally known. Each of these criteria is discussed below.

On the question of use, practically any type of actual use is sufficient. For example, a merely abstract idea, conceptualized by someone but not implemented in any way or put to any use, is a bad candidate for trade secret protection. Examples of this type of abstract idea that have been considered to be bad candidates for trade secret protection include proposed names for new or existing products, proposed promotional ideas, and proposed plot ideas for plays, films, or TV shows. However, once such an idea has been reduced to some concrete form or used in some business relationship, it becomes a much better candidate for protection. For example, after an idea is reduced to some material form like a sample product, the likelihood of being treated like a trade secret is improved. The likelihood of protection is similarly improved if the idea is the subject of a business obligation such as the obligation to furnish improvements, conduct the R&D activities, etc, which often are present in R&D cooperations and complex licensing arrangements.

On the question of whether the use is considered to be in a trade or business, the courts have been even more permissive than they have under the first criteria of use. For example, even non-profit government or university research is often considered to be within a trade or business.

On the question of whether the use is in secret, the courts are noticeably stricter than they are under the first two criteria. The owner of the putative trade secret must actually exercise all reasonable safeguards to insure that secrecy is maintained. These safeguards are especially important if the owner would like to disclose the secret to some licensee.

A number of best practices have emerged for maintaining the secrecy criterion. Limit access to the information to only those members of your own team who actually need to have access to further your team's business objectives, such as by maintaining the information behind locked doors or within locked storage, by marking copies of any relevant documents with clear labels of confidentiality, limiting their routing and distribution, and in all respects actually keeping them confidential. For all key team members who have access to this confidential information, follow careful pre-release review procedures to ensure that none of their speeches or other publications contains confidential information. Use signs and labels to inform and remind both team members and outsiders that certain locations are likely to contain confidential information and that certain information is confidential. Whenever disclosing the confidential information to team members or to outsiders like licensee's, be sure to execute binding contracts with them to obligate them to follow similar secrecy-maintaining practices.

Finally, on the question of whether the information sought to be protected as a trade secret is not generally known, courts generally are fairly permissive. Absolute secrecy is not required. Courts recognize that information can be known to but kept secret within some companies in an industry and still be of competitive value against others in the industry. Similarly, information may even be widely known within one field or industry but of trade secret value as applied to other fields. Lastly, even information that strictly-speaking is out in the open can function as a trade secret. For example, it sometimes is less expensive, but not significantly less effective, to hide certain information "in plain sight" against the background of a massive amount of distracting information that has the effect of causing the reasonable observer to be essentially confused by an information overload problem. The inverse strategy also can yield information protectable by trade secret laws. For example, it can be of significant competitive value to observe and then aggregate information about patterns in pedestrian, vehicular, or internet traffic by monitoring well traveled public spaces, thoroughfares, and electronic communication channels like the Internet.

2. Enforcing Trade Secret Rights

Trade secret owners generally will have causes of action against those with whom they have some relationship, even an indirect relationship; but trade secret owners generally do not have rights against those who are truly independent third parties who in good faith gain access to or independently develop the subject matter of the trade secret. The basic rights of a trade secret owner are to prevent the unauthorized use or disclosure by those who have learned of the trade secret subject matter through a relationship with the trade secret owner. The relationship protecting the trade secret can be one of express contract, or implied from character of some broader relationship, such as employer-employee, or other fiduciary duty of care or loyalty.

Agreements containing express obligations of confidentiality and nondisclosure that are often used to protect trade secrets are most likely to be enforced if they have been entered into after an arm's length negotiation between commercially savvy parties and have been actually enforced. As a result, the more that there is a disparity in bargaining power between the parties at the time the contract was entered, especially if in the employment setting, the less likely there will be full enforcement. Similarly, if the parties themselves fail to consistently follow and enforce their own confidentiality obligations, courts also will be less likely to enforce. In addition, courts will be less likely to enforce where the contract terms directly conflict with some other public policy goal, such as the protection of employees as discussed below.

At least two special notes must be considered when trade secret contractual relationships are with employees. First of all, when hiring new employees, it may be temping to encourage them to use for your benefit any trade secrets they have obtained from their prior employment. But such use may make both you and your new employee guilty of trade secret misappropriation, exposing your own business to potentially serious liability. For this reason, it often is a good practice to avoid this practice and even to educate new employees about trade secret law and encourage them to keep faithful to any legitimate secrecy and use restrictions that they may have with prior employers. Second, when endeavoring to restrict what present employees may do with

your own trade secrets, it is important to realize that courts often will only enforce such restrictions to the extent they are reasonably tailored to protecting your legitimate business interests. For example, covenants not to compete or not to work for competitors generally will be enforceable only to the extent they are reasonable in duration, territory, and scope of activity. One practice that often is used to increase the enforceability of a covenant not to compete is for the employer to agree to treat the soon to be former employee as an ongoing employee during the term of the agreement not to compete, paying ordinary salary and other benefits like pension and health insurance, but requiring the employee not to report to the office to do work – a relationship often called "garden leave." This allows the courts to know that the employee is at least able to earn a living while not allowed to work for the next employer.

US courts generally allow employees to make subsequent use of whatever skills, training, and experience have been acquired in past employment relationships. In addition, many courts interpret narrowly against the employer those employment contracts that endeavor to assign ownership of information generated by an employee. Courts are more likely to enforce such agreements when directed to information developed within the ordinary course of business and are less likely to enforce when directed to information developed outside normal business hours.

The typical remedies for trade secret misappropriation include actual damages and an injunction at the end of the case. Preliminary injunctions also may be available at the beginning of the case to prevent the misappropriation from continuing during the lawsuit.

Preliminary injunctions generally are available if the plaintiff can show a likelihood of success on the merits of the case and irreparable injury if the alleged misappropriation is not stopped immediately. Some courts consider the irreparable harm to be present when it is shown that the defendant is enjoying a significant commercial advantage from the misappropriation. But a more modern trend against injunctions in IP cases may signal that this is not sufficient to receive a preliminary injunction. The trade secret

owner may have to show some greater harm not compensable with money damages such as the potential destruction of the secrecy itself. It also is common in cases in which a preliminary injunction has been granted for the defendant to obtain a court order that the plaintiff post a bond to insure against the harm that the defendant may suffer during the pendency of the litigation if the court ultimately does not find there to have been trade secret misappropriation.

Injunctions are much more likely to be granted at the end of the case after there has been an adjudication of trade secret misappropriation, but even these are not guaranteed. Although many contracts contain clauses that expressly state that their breach will give rise to irreparable harm and that injunctive relief is appropriate, courts often conduct their own determination of whether to grant an injunction.

Damage awards are common in trade secret cases. One element of the damage calculation may be the loss of the value of the trade secret. Another may be a reasonable royalty. In addition, because trade secret misappropriation often occurs through some act of bad faith or infidelity, it is not rare to see awards under more speculative damages theories. Courts sometimes also award punitive or exemplary damages. Attorney fees are less commonly awarded, but the likelihood of award is greater if there is an underlying enforceable contract between the parties that expressly provides for attorney fees to be awarded to the prevailing party.

Criminal liability may even be available in more extreme cases of outright theft. But the prosecutor must be convinced to bring a separate criminal case.

B. Contract

Contract law is a matter of state law that varies state by state to some degree. This discussion will focus on the basic framework of contract law that is common across states, and highlight some important areas in which states differ. Generally, parties are free to structure their contracts as they wish in the US. The typical remedy for breach of contract is a damage award designed to account for the amount of benefit that would

have been conferred by the performance of the contract as expected at the time the contract was formed.

1. Obtaining Contract Rights

Although in the US contracts generally are enforceable whether they are express or implied, written or oral, it is standard practice in commercial matters to have at least some written document purporting to reflect the entire agreement of the parties. Even when formal contract rights have not been created, US courts will sometimes consider a theory of so-called quasi-contract or unjust enrichment. The general rule for this quasi contract approach is that even where there is no legally enforceable contract between the parties a court will allow some relief to prevent unjust enrichment if one party has conferred a benefit on the other, the conferring party had a reasonable expectation of being compensated, the benefits were conferred at the express or implied request of the other person, and unjust enrichment would result if the benefit that was conferred were allowed to be retained without compensation. Some courts will generally be open to arguments for quasi contract relief at all times. Other courts are most closed to these arguments when the parties actually have engaged in express contracting on the same or related issues, under the theory that in these cases the parties have elected to make themselves bound to only those terms over which they have expressly contracted.

Historically, contract formation required both offer and acceptance. The general rule is that an offer must communicate an objective manifestation of intent to be bound by setting forth in a definitive way the essential terms of the proposed contract as well as the person to whom it is directed. An offer is said to create in the offeree the power of acceptance. Many communications fail to set forth either the material terms of the contract or fail to identify specific people to whom they are addressed, and so are only treated as preliminary negotiations or invitations to negotiate rather than as offers. For example, most advertisements are not treated as offers because they do not indicate which specific people can respond to them in a way that will create a binding contract. An offer must be communicated to the offeree to be effective. Offers generally are held open for a reasonable period of time; but parties can and often do enter into binding

contracts that hold offers open for longer in order to create options. Absent a legally enforceable contract to hold an offer open as an option, or reasonable detrimental reliance by the offeree, offers may be revoked. Offers also are treated as revoked if there is death or destruction of the subject matter of the proposed contract.

The general rule is that an acceptance is only something that clearly manifests assent to the terms of the offer and a willingness to be bound by it. The traditional rule under the common law is the so-called “mirror-image rule,” which requires that the response to the offer must be the exact mirror image of the offer to constitute an acceptance and that any additional or different terms will make the response not an acceptance and instead a rejection and counter offer. In such a case, the one who made the initial offer is now the one who has the power to accept. When there are multiple communications passing back and forth between the parties and those communications contain multiple terms it is often difficult to determine which of these communications, if any, is a valid offer; and which, if any, is a valid acceptance of that offer. Courts sometimes will look to the overall behavior of the parties to determine whether a contract has been formed, although determining what exactly are the terms of the contract in these cases is a matter of substantial dispute. This is one reason it is common for parties in commercial matters to reduce their agreement to writing, signed by both parties. Such documents are often treated as the offer and the signature is treated as the acceptance.

Contracts in the US also must be supported by consideration in order to be enforced. The general rule is that both sides to a contract must transfer something to the other side and those transfers must generally be in response to each other. Commentators see the requirement for consideration as a way to ensure that there was a bargained-for exchange between the parties. Courts generally do not enquire into the adequacy of consideration, although something that is truly of token value or is in name only, will not count. All that is generally required is that each party to the contract incurs some detriment by agreeing to do something he is otherwise not obligated to do or by refraining from something he has a right to do. Some courts instead require only that the potential consideration be of benefit to the other party.

If one side to the potential contract fails to provide any consideration, then the contract is said to lack mutuality and is not enforceable. A commonly seen clause in commercial contracts that may create a lack of mutuality is a reserved discretion clause under which one side to the contract is given the discretion to continue to be obligated. If this discretion is truly unconstrained, then the contract will not be treated by the courts as having been supported by consideration. If the discretion is constrained in some way, such as by the duty of good faith, then courts will be much less likely to treat this as a fatal consideration problem. Many courts will imply this duty of good faith into a contract that otherwise does not expressly provide for it. Although courts do require that there be consideration on both sides of the contract, courts generally do not require that the consideration for one side be balanced or fairly matched with the consideration on the other side.

If no consideration is present, courts may still enforce the contract under the doctrine of promissory estoppel. Promissory estoppel requires that there have been reasonable detrimental reliance that should have been expected, and injustice that would result if enforcement were not allowed. Importantly, most states that allow promissory estoppel to function as a substitute for consideration also limit the amount of recovery ultimately awarded as damages to be limited to the amount a court thinks is required by justice, which typically is less than the full expectation damages usually awarded in contract cases.

Other formation defects that are common in commercial contracts include problems of mistake. A mutual mistake concerning a basic assumption on which the contract was based that has a material adverse effect on the contract may leave the contract unenforceable if the adversely affected party did not assume the risk of the mistake. Generally, unilateral mistake is not a defense to formation unless the other party knew or should have known of the mistake. Misrepresentation and fraud may be valid defenses to formation if they go to a material term. If the misrepresentation was willful, constituting fraud, then the defense to formation also requires a showing of mere actual

reliance. If the misrepresentation was not willful, then the reliance must also have been reasonable to create the defense to formation.

Many written commercial contracts contain a large number of clauses that are sometimes labeled “representations,” sometimes labeled “warranties,” sometimes labeled “covenants,” and sometimes labeled with two or three of these terms. A representation is a statement about the existence or nonexistence of a fact, state of affairs, or state of mind at the time the contract is formed. If a representation is not correct, then the other party may have a good argument that there exists some defense to formation such as mistake or misrepresentation. A warranty is usually treated as a promise that some fact will exist in the future after formation. A covenant is a promise to do or refrain from doing certain acts in the future. Because warranties and covenants are promissory in nature, if they are not fulfilled, they may give rise to an action for breach.

2. Enforcing Contract Rights

An essential step in any contract enforcement action is the process of contract interpretation. Generally, contracts are construed with all of their terms considered together, according to their ordinary meaning. Often, ambiguities are construed against the party who drafted the document. Courts also usually look to past conduct of the parties, as well as to custom and usage in the industry. In addition, courts also imply a duty of good faith and cooperation into most US contracts.

Generally, under the so-called parol evidence rule, evidence of a prior or contemporaneous agreement that contradicts, modifies, or otherwise varies the terms of a written contract will not be admissible of the written contract is intended by the parties to be the complete and final expression of the parties’ contract. The presumption that the written contract is, in fact, the final expression of the parties’ intent, is strengthened by the use of a clause in the contract that often is called a merger clause or an integration clause and that states that the written contract is complete on its face.

Although the parol evidence rule is widely enforced, it is limited in practical effect. Courts generally will consider evidence of formation defects such as lack of consideration or the failure to pay consideration that is recited in the contract, fraud, misrepresentation, or mistake, evidence of conditions precedent to the contract, evidence of the parties intent regarding ambiguous terms, evidence of a collateral agreement, or evidence of a subsequent agreement.

In addition to impacting the parties to the contract, contracts also can impact third parties or non parties. Third parties to a contract may have both rights and obligations relating to the contract.

A third party beneficiary to a contract may have rights to enforce the contract if the third party is an intended beneficiary. A third party can enforce the contract only when its rights have vested. Vesting occurs when the third party manifests assent in a manner requested by the parties, brings suit to enforce the contract, or material changes position in justifiable reliance on the promise. Prior to vesting, the parties to the contract are free to modify or rescind the beneficiary's rights in the contract.

Generally, parties to a contract can assign their rights in a contract and may delegate their duties to a contract. Assignment of rights is generally allowed unless it would materially change the obligor's duty or risk. Assignment generally is not allowed for future rights in contracts that are, themselves, in the future. Future rights generally are assignable only in contracts that are in existence. Some assignments are prohibited by law, such as assignment of an employee's wages.

A clause that purports to prohibit the assignment of a contract will generally be construed as barring the assignment of only the assignor's duties. A clause purporting to prohibit the assignment of rights generally does not bar assignment but instead only gives the obligor a right to sue for damages causes by the breached promise to not assign. Assignments generally will be treated as ineffective if assignee is on notice of a promise not to assign or of the contract provides that attempts to assign will be void.

Generally, all duties may be delegated, unless the duties involve personal judgment or skill, delegation would change the obligee's expectancy, a special trust was placed in the delegator by the other party to the contract, or there is a contractual restriction on the delegation.

An additional duty that is assumed by all third parties to contracts in the US is the duty to generally avoid interfering in the business relationships of others. Interfering with a contractual relationship may be actionable as a tort.

A number of limits exist on the obligation of a party to perfectly perform the obligations created by contract law in the US. The duty to perform may be discharged by the occurrence of a condition stated in the contract. The duty may be discharged by objective impossibility such as death or incapacity of a person necessary to the contract, a subsequently enacted law that renders performance illegal, or destruction of subject matter essential to the contract's performance that was not the fault of the party otherwise obligated to perform. Death or destruction will not operate to discharge the duty to perform if the services to be performed by the deceased or the role of the thing destroyed are not so unique that they cannot be replaced. Performance also may be discharged by impracticability that is unanticipated in that the risk of its occurrence was not allocated in the contract, truly extreme, and would make it unreasonably difficult for performance to occur. Performance may be discharged by frustration of purpose if the frustration is caused by an event that was not reasonable foreseeable at the time of contracting, if this destroyed the purpose of the contract, and if the purpose was understood by both parties at the time of formation. Mutual rescission generally will operate to discharge the duty to perform, but rescission will not be allowed if the rights of a third party beneficiary already have vested in the contract.

Even absent discharge, perfect performance is not required. Only breach that is determined to be material will give rise to an immediate right to suspend or cancel. Substantial performance (as compared with perfect performance) generally will only give rise to a right to sue for actual, objectively measurable and provable, diminution in value caused by the imperfect performance, not the cost of perfect performance or

difference in value between the imperfect performance and the subjective value to the non breaching party of perfect performance.

The most common remedy for breach of contract is expectation damages. Expectation damages are designed to put the non-breaching party, in the position they would have been in absence of breach. They can be viewed as a substitute to performance.

Reliance damages also may be available. Reliance damages are designed to put the non-breaching party back where they were before the contract was formed. The general rule is that reliance damages are not available unless expectation damages are too speculative.

Sometimes, restitution damages are available. Restitution damages are designed to put the breaching party back where they were before the contract was formed. The rule is that restitution damages are generally only available where the non-breaching party has transferred a benefit to the breaching party and would constitute the value of that benefit.

Consequential damages generally are not available. The general rule is that consequential damages are only available to the extent that a reasonable person at the time of entering into the contract would have foreseen that such damages would result form breach. In practice, parties significantly increase their chance of obtaining consequential damages if at the time of contract formation they make clear to the other party the full extent of the consequences that are likely to follow from beach.

Punitive damages are generally not allowed in commercial contract cases. Punitive damages generally are available only in extreme cases in which in addition to breach of contract there is some separate tort.

Sometimes, parties to a contract will endeavor to write into the contract a so-called liquidated damages provision that expressly states what the damages will be if there is breach. Such a clause generally will be valid only if the damages were difficult to ascertain at the time the contract was formed and the amount agreed upon was a reasonable forecast of the actual harm that breach would cause.

Regardless of the damages theory that is pursued, the non-breaching party generally has a duty to mitigate damages. The rule is that if a party does not mitigate, then their damages award may be decreased by the amount that might have been avoided.

The remedy of specific performance is rarely available in addition to damages. Courts will not order specific performance unless it is easy to administer, the balance of hardships tips in favor of the plaintiff, and there is no great harm to society. Generally, courts will only consider the legal remedy of damages to be inadequate where the subject matter of the contract is unique, such as if it is land or unique goods.

C. Patent

Patent law is a matter of federal law in the US and so is generally uniform across the country. Patents rights are obtained from the Patent Office and generally are available are all areas of technology. Patents generally provide a right to exclude others from making, using, selling, offering for sale, or importing the patented subject matter. Because intent and copying are generally not elements of the patent infringement analysis, patents are effective against even third parties who independently invent the patented subject matter. The remedies for patent infringement are generally somewhat stronger than for trade secret infringement in that patentee's generally can obtain either lost profits or at least a reasonable royalty as damages, and probably can obtain a permanent injunction.

Generally speaking, the power of the patent comes from the patent grant of a right to exclude. Note that a patent gives no right to use. So, if A has a patent on a widget, the patent gives A no right to use the widget, it only gives A the right to exclude others from using the widget. A may or may not be facing other restrictions on the use of the widget and as a result A may or may not be able use the widget. But regardless of A's right to use, the patent may still be of great value to A because with the patent A has the power, backed by the Federal Government, to exclude others using the widget. And A generally can elect to use this power to exclude and obtain an injunction from a federal

court preventing others from using the widget, or A may grant permission to others to use the widget in exchange for some licensing fee.

1. History and Philosophy of Patent Rights

Article I, Section 8, Clause 8 of the Constitution gives to Congress the power to promulgate patent laws and the US has had a patent system in place over 200 years ago, soon after the founding of the country. The present patent system is codified in Title 35 of the United States Code (35 USC §§ 1 et seq.), and generally was implemented in the 1952 Patent Act ('52 Act).

The '52 Act was drafted by Giles S. Rich, at the time a well-known patent attorney in New York City, and former President of the New York Patent Law Association, along with P.J. Federico, Examiner in Chief of the Patent Office, and attorneys Henry Ashton and Paul Rose. The Bar's goal in appointing Rich to draft the '52 Act was to bring more predictability to the patent system and to reverse trends in Supreme Court case law that weakened patent enforcement through the broad use of antitrust principles and that made it more difficult to even obtain patents in the first instance. Rich was appointed by President Eisenhower in 1956 to be a federal appellate judge on the United States Court of Customs and Patent Appeals, predecessor court to the United States Court of Appeals for the Federal Circuit, where he eventually became the oldest active Federal Judge in the nation's history, until his death in 1999, by which time he had become long and widely recognized as the Dean and Father of American Patent Law. This brief history is not merely a tribute to Judge Rich. Knowledge of the origins and policies of the present patent system can help a lawyer understand and argue many difficult issues that arise in practice, especially in contentious battles over what is patentable and what constitutes infringement, patent misuse, or an antitrust violation. The writings of Judge Rich, which span almost 70 years in the patent business, provide an excellent resource for those interested in sound and practical teaching about how the patent system does and should operate.

The ’52 Act was primarily passed to achieve three goals: (1) to codify the patent system; (2) to statutorily overrule a set of cases that had effectively eroded patent rights through the doctrine called patent misuse; and (3) to statutorily resolve a dispute between two lines of cases relating to the standard for patentability by selecting the objective standard called non-obviousness. Premised on the view that predictability would best suit all those impacted by the patent system, the wisdom of the ‘52 Act was applauded by the leading jurists and thinkers in commercial law of the time, such as Learned Hand and Jerome Frank.

Generally, although the US patent system recognizes that patents can provide incentives to invent, a central goal of those drafting and implementing the ’52 Act was on the complex process of getting inventions put to use, not on the process of invention itself. This focus on commercialization permeates the patent system created by the ’52 Act.

Treating patents as property rights backed up by rights to exclude provides significant incentives for parties to collaborate, helping to solve a key problem that would otherwise frustrate the socially constructive coordination that facilitates commercialization of innovation. Bringing an invention to market requires coordination among its many complementary users, including developers, managers, laborers, other technologists, financiers, manufacturers, marketers, and distributors. This socially constructive coordination depends in at least two fundamental ways on the expectation that patents will be enforced with strong property protection like an injunction, as compared to weaker, liability rule protection like a compulsory license.

First, the credible threat of exclusion associated with a published patent acts like a beacon in the dark, drawing to itself all those interested in the patented subject matter. This beacon effect motivates these diverse actors to interact with each other and with the patentee, starting conversations among the relevant parties.

Although so many on the so-called “pro-patent side” of the patent literature, like Joseph Schumpeter and Edmund Kitch, maintain that the patent owner should be able to

control uses, the commercializing view of patents shows why we should be agnostic about who should control the ensuing negotiations. Because we cannot know ex ante who will be best for that role, we should leave this determination to the particular facts of each negotiation. As the beacon effect highlights, facilitating coordination among interested parties is a less aggressive goal than assigning control to a particular party like the patent owner.

Second, the widespread expectation that the patent will be enforced motivates each of these parties to reach agreement with one another over the use and deployment of the technology. This bargaining effect falls apart if the parties are unsure the patent will be enforced because, in that case, there is significantly less need to reach agreement ex ante. The fear of weak enforcement creates a disincentive for the necessary parties to work together at the outset.

The patent literature has not devoted much focus to the mechanism by which this breakdown occurs. While Robert Merges focuses on how property rules give patent owners access to more remedies than liability rules, which in turn give them greater control, it is important to see how property rule treatment improves incentives for everyone in the bargaining process, not just the patent owner. Smith, Merges, and Richard Epstein have all examined the information cost advantages of property rules in their scholarship, and work by Louis Kaplow and Steven Shavell has explored the risk that liability rules will lead to undercompensation of property owners because of multiple takings. But none of these patent scholars focuses on how adopting liability rather than property rules can impede coordination among takers and dissipate the incentives that parties other than the patent owner have to consummate a deal.

Knowing there is a good chance that a court employing a liability rule approach will set a lower price than the patent owner would accept, some potential infringers may first try for a low damage award from the court, rather than consummate a deal up front with the patent owner, and then later make a deal later if the court award is too high. The prospect that infringement may be an attractive option to some can decrease the

incentives for all others to attempt or consummate a deal ex ante, thereby weakening both the beacon effect and the bargain effect.

In addition, while liability rules focus on price, deals involving patent often hinge on complex terms other than price, especially early in the process of commercializing new technologies. These terms often involve assets that are difficult to hedge, diversify, or insure, such as a particular individual's unique skills, time, and relationships, as well as specialized technical support, field-of-use or territory limitations, grant-backs, cross-licenses, payment schedules, and most-favored-nation provisions.

The problem is that a court-imposed damage award, which is emblematic of liability rule treatment, is in all but the rarest of cases reduced to a simple monetary amount. The promise of some share of a possible damages award does little to mitigate risk of loss of these other relatively unique assets for either the IP owner or the other parties involved.

For this reason, the helpful strategies explored by Ian Ayres for achieving similar or even superior results through liability rules hinge on whether those impacted are portfolio players. That is, Ayres' strategies favor those large, portfolio players who can more easily hedge, diversify, and insure the assets they are considering investing in these deals over smaller players making unique investments. For these smaller players and others relying on unique assets, though, property rules are more likely to protect their interests, thus helping them to coordinate.

2. Rules on Patentability

Patents are available for essentially any useful product or process that is new and would not have been obvious to a person having ordinary skill in the art (PHOSITA) provided that the patent application, and issued patent, contains a detailed written description of the invention sufficient to enable those in the art to make and use it and contain one or more claims particularly pointing out and distinctly claiming the invention, and the application divulges the applicant's best mode of making and using the invention. As will be discussed below, patentable subject matter is generally considered to be very broad in the US and includes "anything under the sun that is made by man."

(Diamond v. Chakrabarty 447 U.S. 303 (1980) (Burger, C.J.) (quoting P.J. Federico's congressional testimony on bill leading up to the '52 Act)).

To obtain a patent, the inventor must file a patent application with the United States Patent and Trademark Office, in Washington, D.C., which examines the application to help determine whether these requirements are met. The cost, largely in fees to attorneys, to get a patent issued can range from several thousand dollars to several tens of thousands of dollars. The bulk of this expense often is in the initial drafting phase, since compliance with the patent law disclosure requirements, as discussed in more detail below, is generally tied to the disclosure that is originally filed, providing patentees with strong incentives to file very detailed initial disclosures.

(a) Novelty

Patent law's novelty requirement helps insure that the patent right to exclude will not impose restraints on the liberties, or investments, of others. If others are practicing the invention before the patentee, then the patentee's work is not new and is not patentable. So, when the holder of a valid patent on an invention that was new acts to exclude someone, the patentee is not really guilty of "taking" but merely of "teasing." The patentee does not stop others from doing what they were doing. The patentee merely discloses how to do it and is then given the power to stop others from doing it. Patent law has a detailed set of rules that operate to help make sure that the patent does not give power over someone who was actually doing it first. These rules prevent patents on stuff that is not new at the time the patent applicant makes his invention and also provide incentives for the applicant to file his application soon after that date of invention. The rules governing novelty and anticipation prevent patents on stuff that is not new. The rules governing the statutory bars provide incentives to patent soon after invention by barring patent protection if the application is not filed within one year of the applicant's publication, public use, or sale of the invention.

If the invention is not new, it is said to be anticipated by the prior art. The prior art is essentially the world of public information that existed prior to the patentee's date of invention.

Information is available as prior art if it qualifies under one or more of the subsections of Section 102. Information is available as prior art if before the applicant's date of invention it was known or used publicly in the United States or patented or described in a printed publication anywhere in the world. (35 USC §102(a)). Even a student thesis can count as a printed publication, as long as it is stored in someplace that is publicly accessible and it is cataloged in some meaningful fashion, such as by topic. (See In re Cronyn, 890 F.2d 1158 (Fed. Cir. 1989)). Information is also available as prior art if before the applicant's date of invention it was described in someone else's patent application that ultimately issued in some patent. (35 USC §102(a)). Information is available as prior art if the applicant derived his invention from that information, even if that information was not public. (35 USC §102(f)). Lastly, information is available as prior art even if it was not public and the applicant did not derive his invention from it, as long as it was not abandoned, suppressed, or concealed. (35 USC § 102(g)). This type of prior art can be particularly pernicious in litigation over validity and requires at least some corroborating evidence, beyond mere oral testimony of the alleged first-inventor. (See Finnigan Corp. v. Int'l Trade Comm'n, 180 F.3d 1354 (Fed. Cir. 1999).

A patent claim is invalid for anticipation under Section 102 (35 USC § 102) if any single item of available prior art discloses, either expressly or inherently, each and every limitation of the claim in a manner sufficient to enable one skilled in the art to reduce the invention to practice. Some evidence outside of that single item of prior art may be considered, but only to explain that prior art to the decision-maker and aid in his determination of what that prior art would have meant to a PHOSITA, but not to fill gaps in the reference. As always in patent law, the name of the game is the claim – so the comparison here is between the patent claim and a single item of prior art and for anticipation there must be identity between the two. Anticipation is a question of fact.

In cases where the prior art is a pending application or an issued patent, and it is a claim in that prior art, rather than some other part of the disclosure, that covers the same subject matter as the claim of the present application or patent, then the battle is not merely one of validity, but rather is a battle over which inventive entity is entitled to the patent claim. Such priority disputes for a patent claim are fought in quasi-litigation procedures before the Patent Office called interferences, and the patent claim will be awarded to the one who was first to conceive of the invention and diligently reduce it to practice. (35 USC § 102(g)). These interference proceedings are the central difference between a first-to-invent system that we have in the US and a first-to-file system that exists in most other countries. In the US, the interference proceeding is needed to determine who was the first to invent, which is a more complex determination than determining who was the first to file.

(b) Statutory Bars

Even if the patent applicant was the first to conceive and reduce to practice the invention, he may still be barred from obtaining a patent thereof if the invention is publicly used, sold, offered for sale, printed in a publication, or patented in another country more than one year before the application is filed. (35 USC §§ 102(b) and (d)). These statutory bars should be seen as providing a one-year grace period in which to file a patent application after the invention is complete and put into use because they are unique to the US patent system – most of the world's patent systems have an absolute novelty requirement measured from the time of filing the patent application. What constitutes a public use or sale under these bars has been a topic of great debate and much confusion in the case law and academic commentary for many years. Two famous cases highlight the tension. In Egbert v. Lippman, 104 U.S. 333 (1882), a quite private use – of steel springs in the corset of a single woman who was a loyal and "intimate friend" of the inventor – was held to have been "use in public" in part because it was carried on for two years before the patent was filed. In City of Elizabeth v. American Nicholson Pavement Co., a quite public use – of a pavement surface – was held to have been merely "experimental." Most recently, in Pfaff v. Wells, 119 S. Ct.

304 (1998) the Supreme Court announced that the proper test for the on-sale bar is whether the invention was “ready for patenting” at the time of the sale or offer for sale. For the pubic use bar, the factors courts will likely consider include the confidentiality of the use, the control over the use by the patentee, and the monitoring of the use by the patentee and the desire for “feedback” – such as to show its experimental nature. When in doubt, file a patent application within one year of first use. And, if interested in obtaining patent rights in other countries, the applicant should file immediately.

(c) Nonobviousness

The patent system has long refused to grant patent on inventions that are merely new, imposing some additional requirement for patentability that seemed to be based on the differences between the claimed invention and the prior art. Unfortunately, the exact nature of this additional requirement was very malleable, hard to understand, and easily used by courts that had developed an antipathy to patents during the post-Depression era. Before the ’52 Act, case required that to be patentable, an invention had to be an “invention,” which hardly gave guidance to the Bar and to industry. And courts were using the requirement for “invention” to strike down countless patents as a measure of last resort. Things had gotten so bad by 1949 that Justice Jackson remarked in dissent that there had come to exist a “strong passion in this Court for striking [patents] down[,] so that the only patent that is valid is one which this Court has not been able to get its hands on.” (Jurgenson v. Otsby & Barton Co., 335 U.S. 560, 572 (1949) (dissenting opinion)). A major innovation in the ’52 Act was the introduction into the patent system of an objective additional test for patentability called nonobviousness, which was embodied in Section 103 (35 USC § 103). It unfortunately took the Supreme Court about fifteen years before the impact of Section 103 was recognized, but eventually fate and perseverance prevailed and the law of Section 103 became the law applied in the courts. (See Graham v. John Deere, Co., 383 US 1 (1966)).

According to Section 103 and Graham, the nonobviousness analysis requires a determination of the scope and content of the prior art, a comparison between the claimed invention and the art, the level of ordinary skill in the art, and an assessment of

whether the differences between the invention and the prior art are such that the invention as a whole would have been obvious to a PHOSITA at the time the invention was made. Graham also requires consideration of so-called “secondary factors” such as commercial success, long felt but unmet need, failure of others, and licensing or acquiescence by others.

In practice, Section 103 can be thought of as a second step in a prior art analysis in which items of prior art available under Section 102 may be combined. Under Section 102, the question is whether each and every limitation of a claim is found in a single item of prior art. Under Section 103, the question is whether each and every limitation can be found between two items of prior art – more that two items present a very rare and difficult to win case for nonobviousness. If the claim limitations are spread between two items of prior art, the invention may be found to have been obvious if the art also provided some suggestion or motivation to combine those two items of art and some reasonable likelihood of success in achieving the claimed invention upon their combination. Nonobviousness is ultimately a legal determination, based on subsidiary questions of fact.

The recent US Supreme Court decision in the KSR case is seen by many as having raised the bar for the obviousness standard by injecting more discretion into the determination of this central issue for most patent cases. (See KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007)). The central issue presented in the KSR case is whether expert opinion testimony in court when adopted at the discretion of a federal judge is enough to prove what would have been obvious to a person having ordinary skill in the art of the patentee at the time in history when the patentee made an invention. Patent critics see the KSR case as standing for the proposition that government decision-makers like judges now have increased discretion to pronounce what the prior art teaches; and they applaud that result, hoping to see it applied in court and during initial Patent Office examination. For example, examiners would be able to block patents on the basis of their own assertions about what the state of the art was at a particular time in history, without having to rely on the factual proof, such as

documents and sample products, which has long been required. Others think the case was narrowly decided on its facts and that the relevant inquiry remains an objective determination of precisely what was taught by the particular combination of relevant pieces of prior art.

(d) Disclosure Requirements

The disclosure requirements of patent law are at least as important as the prior art-based requirements of novelty and nonobviousness. Indeed, in rapidly moving fields of technology, such as biotechnology, many of the leading cases over patent validity are based more on validity issues arising out of the disclosure requirements, than on validity issues arising out of the prior art. Patent law's disclosure requirements come from Section 112 of the Patent Act. (35 USC § 112). Section 112 governs the patent specification. The term "specification" refers to the entire substantive written content of the patent application and the issued patent – the supporting text and drawings as well as the claims. Typically, the specification contains many pages of descriptive text explaining the background and operation of the invention. Always, the specification concludes with one or more claims. The first paragraph of Section 112 sets forth three distinct disclosure requirements: [1] written description; [2] enablement; and [3] best mode. The second paragraph of Section 112 provides a fourth requirement: [4] the specification must conclude with one or more claims particularly pointing out and distinctly claiming the invention.

The purpose of Section 112's written description requirement is broader than merely to explain how to make and use the invention; the requirement ensures that the specification as filed conveys with reasonable clarity to a PHOSITA that as of the filing date sought for the eventually issued claims the patent applicant was in possession of the specific thing covered by those claims. (See Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-63 (Fed. Cir. 1991)). The written description helps identify the "blaze marks" along the trial through the forest, so competitors and would-be infringers can know where lies the restricted turf of the claims. (See In re Ruschig, 379 F.2d 990, 994-995 (C.C.P.A. 1967)). An applicant satisfies the written description requirement "by

describing the invention with all its claimed limitations, not [merely] that which makes it obvious . . . . One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." (Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997)). Satisfaction of the written description requirement is a question of fact.

Modern claims to genes or gene fragments provide a great example of the interaction between the written description requirement of patent law and the real commercial desires of patent applicants. In the case of claims to a particular gene or protein, a proper written description must give more that its biological or other function, and must rather set forth "a precise definition, such as by structure, formula, chemical name, or physical properties." (Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993)). A patent claim directed only to a specific DNA sequence discovered by the applicant will likely not likely be of great commercial significance, because a mere change in a few base-pairs of the sequence may completely avoid infringement. To make this claim broader, the applicant will want to claim at least the other alleles of the same gene, and the gene in other species.

To do so, the applicant may try to claim the sequence and anything that "hybridizes" to it under moderately or highly stringent conditions. Remember, DNA sequences ordinarily exists in pairs, forming double stranded helices and the "rules" of DNA binding teach that sequences that are identical to each other will be able to bond together – or "hybridize" – under conditions like temperature and pH that are relatively harsh, or stringent. In contrast, under such stringent conditions sequences that are not highly similar will fail to bind together and form double helices. So, the amount of stringency can be a way to "dial up" or "dial down" the level of similarity between DNA sequences one can identify through a binding process. This gives the drafter of patent claims for genes some flexibility in claiming sequences that are similar to the specific one the applicant has first found. But the catch, here, is that to support such flexible claims under the written description requirement, the disclosure must give real details about the precise conditions of binding and the precise regions of the DNA that patentee

considers to be most important. The costs of providing such a detailed written description can make the filing of a patent application with broad claims in any fast-moving field like biotechnology significantly more expensive in both attorney and client time. But this may be a prudent investment, for a skimpy description may lead to only the narrowest of claims in the application or issued being valid, if any.

Section 112, first paragraph, also requires that the specification as filed enable a PHOSITA to make and use whatever is covered by the claims as issued without undue experimentation. Careful attention to every parameter is a prudent guide for satisfaction of the enablement requirement. Particularly in a fast-moving or unpredictable technology, the applicant may not be able to "bootstrap a vague statement of a problem into an enabling disclosure." (Genentech, Inc. v. Novo Nordisk, 108 F.3d 1361, 1366 (Fed. Cir. 1997)).

However, it is recognized that "a patent need not teach, and preferably omits, what is well known in the art." (Hybritech v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986). As a practical matter, a common way to navigate the risks of an failing to provide enabling disclosure while wanting to avoid writing a massive specification is to write a just a large specification that includes many parameters in addition to a liberal citation and incorporation by reference of published technical literature. Incorporation by reference of publicly available materials may provide a convenient method for satisfaction of the enablement requirement. (See In re Hawkins, 486 F.2d 569 (C.C.P.A. 1973); In re Hawkins, 486 F.2d 577 (C.C.P.A. 1973)). Satisfaction of the enablement requirement is ultimately a question of law.

The first paragraph of Section 112 also requires that the application as filed must divulge the best mode known by the applicant of carrying out the invention covered by the claims as eventually issued. There are both subjective and objective components to this requirement. The inquiry first looks to determine whether the inventor did have some subjective best mode, which is a factual question. The inquiry then looks to see whether this better mode, if any, is objectively disclosed in the specification as filed, which is largely a legal determination based on the enablement requirement discussed

above. Intent to conceal is not required to support a holding of failure to comply with the best mode requirement. (See U.S. Gypsum Co. v. National Gypsum Co., 74 F.3d 1209 (Fed. Cir. 1996)). The best mode need not be labeled as such in the application; it must merely be included. And the applicant has no duty to "supplement" or "update" the best mode during prosecution of the application. Furthermore, the best mode requirement extends only to the actual inventor or inventors, not to their employers or co-workers. (See Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043 (Fed. Cir. 1995)).

The best mode requirement of US patent law is often particularly troubling for foreign inventors because this requirement is not present in most foreign patent systems. The problem is particularly vexing for those who file their patent applications first in a country other than the US and then seek the benefit of this foreign filing date when taking the benefit of the international patent treaty that allows filings in one country to support priority claims in another country. Applications that are first filed outside of the US must be carefully supplemented with any information needed to satisfy the US best mode requirement at the time they are initially filed outside of the US if the benefit of that foreign priority date is desired when the application is eventually filed in the US.

The second paragraph of Section 112 requires that the specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." (35 USC §112 ¶ 2). But this part of the statute is a bit out of date. As Judge Rich has reminded students of patent law "What the inventor regards as his invention has very little, if anything, to do with most claims [because claims] are drafted by attorneys and agents." (Giles S. Rich, Foreword, "Principles of Patent Law," Foundation Press, 1998). As discussed earlier, Judge Rich has often remarked: "the function of claims is to enable everyone to know, without going through a lawsuit, what infringes the patent and what does not." (Hilton Davis Chem. Co. v. Warner-Jenkinson Co, 62 F.3d 1512, 1539 (Plager J., dissenting) (quoting Giles S. Rich, "The Extent of the Protection and Interpretation of Claim – American Perspectives")).

The notice function of claims has lead to some debate about the proper course of action for courts to take when faced with claims that may be indefinite. In a famous case over a patent on a splayed-string tennis racket, the claim in issue had language requiring that the amount of string splay "varies between" two distances. (Athletic Alternatives, Inc. v. Prince Mfg. Inc., 73 F.3d 1573 (Fed. Cir. 1996)). A central issue on appeal was whether the phrase "varies between" required that the amount of string splay take on at least three values – that is two end values and some mid value – or whether the phrase required only two values – that is, two end values. A racket with only two splay distances would not infringe the first interpretation of the claim, but would infringe the second. The majority opinion held "Where there is an equal choice between a broader and a narrower meaning of a claim, and [the other disclosure requirements are sufficiently satisfied with respect to at least] the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning." Senior Circuit Judge Helen Nies, former Chief Judge of the court, wrote in dissent: "The majority, in effect, eviscerates the requirement of Section 112, ¶ 2 for the patentee to particularly point out and distinctly claim his invention while purporting to rely on it." It is not clear whether a claim that is subject to more than interpretation should be invalid for lack of definiteness or limited to the narrower interpretations. Either proposition may be risky, especially since definiteness is ultimately a question of law.

(e) Subject Matter and Utility

The final patentability hurdles a patent applicant may face relate to Section 101 of the Patent Act, which provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." (35 USC § 101). From this single section come two distinct requirements: utility and statutory subject matter, which are each questions of law.

The presence of the word "useful" both here and in Article 1, Section 8, clause 8 of the Constitution, has lead courts over the years to impose some form of "utility" requirement on patents. Although it is not clear what the harm would be of issuing patents on

useless inventions – who would ever infringe a useless patent? – the utility requirement still exists in patent law today, but presents a very low hurdle to patentability. Today, a patent claim likely will be considered sufficiently useful if either (1) the applicant makes has asserted the invention is useful for some particular purpose and that assertion would be credible to a PHOSITA; or (2) if the invention has a well-established utility – such as when a PHOSITA would immediately appreciate why the invention is useful based on its characteristics and similarities to items in the art.

The recitation of precise classes of patentable subject matter in Section 101 has similarly lead to substantial case law about whether particular types of inventions are even eligible for patent protection. Previously, living things, algorithms, computer programs, business methods, and financial services were each considered to be per se excluded from patentable subject matter. But all of this has changed in the past twenty years. In the famous case of Diamond v. Chakrabarty, 447 U.S. 303 (1980), the Supreme Court in an opinion by Chief Justice Warren Burger affirmed a decision by Judge Rich that there is no per se exclusion from patent protection for living things, stating generally: "Congress intended statutory subject matter to 'include anything under the sun made by man.'" (quoting P.J. Federico's congressional testimony on bill leading up to the '52 Act)). Soon thereafter, the Supreme Court in an opinion written by Justice Rehnquist affirmed a decision by Judge Rich that an industrial process is not per se excluded from patent protection merely because it is carried out on computer and uses a mathematical formula. (Diamond v. Diehr, 450 U.S. 175 (1981)). In a case that effectively opened up the field of computer programs to patent protection, and writing for the Federal Circuit in banc, Judge Rich applied the holding in Diehr to a patent claim on a computer program for printing a smooth curve on a compute screen. (See In re Alappat, 33 F.3d 1526 (Fed. Cir. 1994)(in banc)). Most recently, in a case that effectively opened up the field of financial services to patent protection, Judge Rich applied the holding of Diehr to a hub-an-spoke mutual fund accounting system, disposing of the so-called algorithm and business method exceptions to patentable subject matter, in favor of the various prior art and disclosure requirements of patent law

reviewed above. (State Street Bank & Trust Co. v. Signature Financial Group, Inc., 149 F.3d 1368 (Fed. Cir. 1999). Thus, until recently, the touchstone for patentable subject matter is merely that the claimed invention must cause come concrete and tangible result, and as a result, patentable subject matter itself presents a very low hurdle to patentability.

A number of very recent cases suggest that the statutory subject matter and utility requirements may soon become serious hurdles to patent law in the US, but this remains an open question. At least today, and probably for the near future, these requirements are still lower than they are in most of the rest of the world, where a number of exemptions to patentable subject matter are enforced.

(f) Patent Office Examination

US Patent rights are only obtained from the US Patent and Trademark Office ("PTO"), in Washington, D.C. To obtain a patent, an inventor or inventors must file a patent application with the PTO. The Commissioner for Patents is expressly required to "cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Commissioner shall issue a patent therefor." (35 USC § 131). Examination is conducted to ensure that the application complies with the many requirements for patentability discussed above. The writing necessary for a patent application is quite technical and a university degree in a scientific, engineering, or other technical discipline is today generally required for registration to practice before the PTO. (See 37 C.F.R. §§ 10.5, 10.6, 10.7).

The process of arguing to the PTO that an applicant is entitled to a patent is called patent prosecution and can take three years on average, from filing to issuance. The PTO examiner will search readily available sources of prior art, and often engage in significant communication with the applicant's patent counsel, at least in writing but also sometimes including oral interviews. The entire cost of obtaining a patent, which is largely the fees for the patent attorney, can range from around ten thousand dollars to

many tens of thousands of dollars. At least two main factors can impact this cost, and both of these factors are typically implicated for more complex areas of technology: the need to draft a rich, thorough disclosure at the time of filing; and the need to make extensive legal arguments during examination.

In addition, the applicant and the applicant's attorney, agent, or employer, are required to disclose in an "Information Disclosure Statement" any information – such as prior art – that is known to them and that is material to patentability, which is information that would raise at least a prima facie issue concerning patentability. (See 37 C.F.R. 1.56). Failure to comply with this duty to disclose may be constitute inequitable conduct and render the patent unenforceable.

The PTO examiner will consider the results of his independent search as well as the information contained in the applicant's Information Disclosure Statement. Upon such consideration, the PTO examiner will often reject some or all claims in the application as initially filed and will issue a formal paper called an Office Action setting forth the rejection and the reasons therefor. The applicant's attorney or agent will typically respond to the rejections in the Office Action with argument, evidence, or by amending the claims. The applicant may not introduce new matter into the application, itself, during prosecution and new matter is any substantive information not contained in the originally filed application. (See 35 USC § 132). Typically, some or all claims will go through two rounds of rejection and response during patent prosecution. If the examiner decides that all pending claims are patentable, then he will issue a Notice of Allowance and a soon thereafter a US Patent will issue. Patent rights only begin upon the issuance of the patent.

An issued patent is presumed valid. (35 USC § 282). However, it is the federal court, and not the PTO, that is the final arbiter of patent validity. A challenger to a patent bears the burden of proving invalidity by clear and convincing evidence.

If the examiner does not issue a patent, he may ultimately make his rejections final, in which case the applicant may elect to abandon the application, appeal to the Board of

Patent Appeals, or file a continuing application. If the Board affirms the examiner's rejections, the applicant may elect to abandon the application, file a continuing application, bring a civil action in the US District Court for the District of Columbia, or bring a direct appeal to the United States Court of Appeal for the Federal Circuit. (See 35 USC §§ 141, 145).

Continuing applications present a particular set of issues, depending on the type of continuing application. One set of issues is filing date. Another set of issues is patent term. And they are related. Since the US implementation of the General Agreement on Trade and Tariffs (GATT) in 1995, the term of an issued patent is 20 years from its earliest claimed filing date.

A continuing application enjoys the benefit of the earlier application's filing date for any claims in the later application for which there is adequate disclosure – measured by the normal disclosure requirements discussed above – in the earlier application. So, a patent issued from a continuation application will likely enjoy the benefit of the earlier application's filing date but will also likely face a relatively short window of patent life, measured from that same early date but beginning when the patent issues much later.

The requirements for filing a continuation application of any type are (1) copendency – the original application must still be pending when the continuing application is filed; (2) common inventor – the applications must have at least one inventor in common; and (3) reference – the text of the second application must state that it is a continuation of the earlier application. There are three main types of continuing applications: continuations, continuations-in-part, and divisionals. A continuation (CON) is an application has the identical disclosure of the earlier application. A CON is typically used to obtain further prosecution of claims not allowed in the earlier application. A continuation-in-part (CIP) application has some subject matter in common with the earlier application but also has some new matter not originally in the earlier application and only enjoys the earlier application's filing date for the common material, not the new matter. A CIP is typically filed for the purpose of introducing this new matter into the application, such as when new limitations need to be added to better distinguish the

invention from the prior art, or when an improvement on the invention has been made. A divisional application (DIV) is much like a CON, but with different claims. If one or more distinct inventions – such as a product and a process for making or using the product – are claimed within the same original application, the PTO may require the applicant to elect to pursue only one such invention in the prosecution of that application. (See 35 USC § 121). The PTO does so by issuing a "restriction requirement." An applicant typically files a DIV to pursue the claims directed to the invention not elected for prosecution in response to the restriction requirement issued in the earlier application.

The United States also allows applicants to file something called a "provisional" patent application. Provisional patent applications are essentially placeholders. They are not examined and expire in one year. Applicants typically file a provisional application to obtain an early filing date and then have the one-year of opportunity to decide whether to pursue full-blown patent prosecution. A patent that issues from an application that claims the benefit of a provisional application enjoys the early filing date of the provisional application but also enjoys a full term measured only from the regular application's filing date, not from the provisional's earlier filing date.

Finally, although patents are national in scope, the United States is a signatory to the international Patent Cooperation Treaty (PCT). This treaty allows applicants to make one filing in a national patent office designated as a PCT receiving office (the US PTO is one such receiving office) and have that application essentially "count" for priority purposes as though it were filed in the domestic patent offices of any signatory country. Many applicants typically file through the PCT process while simultaneously pursuing a regular US patent application.

3. Rights and Limitations of the Patent Grant

The Patent Act specifically states the every "patent shall contain . . . a grant . . . of the right to exclude others from making, using, selling, offering for sale, or importing the invention into the United States." (35 USC § 154(a)(1)). And the Patent Act also

specifically defines infringement as follows: "whoever, without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term therefor, infringes the patent." (35 USC § 271(a)). The length of patent term begins on the day the patent issues and continues for 20 years measured from the earliest claimed filing date of the patent application. (35 USC § 154(a)(2)). Because prosecution typically takes about three years, effective patent term is typically about 17 years. Pre issuance and post-expiration activities do not, themselves, infringe. The patentee bears the burden of proving infringement, a factual question, by clear and convincing evidence.

(a) Claim Construction and the Doctrine of Equivalents

The focus of every patent is the claim. As a result, the interpretation, or construction, or a patent claim is central to every patent case. The claims must be construed the same for analyses of both validity and infringement.

The combined pressures of validity and infringement play out in a dynamic way on claims and their construction. As Judge Rich used to remind students, patent strength is tied to breadth — the stronger a patent is the weaker it is and the weaker a patent is the stronger it is. A broad claim is strong on offense because it covers more and therefore is more likely to be infringed, but also is weak on defense because it may cover something in the prior art or may fail to be enabled or sufficiently described, and therefore is more likely to be invalid. In contrast, a narrow claim is weak on offense, because it covers less and therefore is less likely to be infringed, but also is strong on defense because it may not cover something in the prior art or may not fail to be enabled or sufficiently described, and therefore also less likely to be invalid.

The construction of a patent claim is a question of law, for decision by the judge, not the jury, and is reviewed de novo on appeal. (See Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996)). A patent is considered by courts to be a fully integrated written instrument, and when courts hear evidence extrinsic to the patent record on claim construction, they are not allowed to consider it as normal evidence, crediting or not

crediting it and making factual findings; the court must instead essentially only use such evidence to inform its understanding of the technology. (See Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (in banc)). When courts construe claims, courts must (1) look first to the claims themselves; (2) always review the rest of the specification to see how the patentee used claim terms, because a patentee may be his own lexicographer and define terms anyway he likes; and (3) review the prosecution history, which contains the complete record of proceedings before the PTO, to determine whether any interpretations were disclaimed during prosecution. (See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576 (Fed. Cir. 1996)).

Once a claim is construed, infringement is determined as a matter of fact. Infringement exists where each and every limitation of the claim is found in the accused process or device. In this sense, infringement is analogous to anticipation, and it is often said: "That which infringes if later anticipates if earlier." (Polaroid Corp. v. Eastman Kodak Co., 789 F.2d 1556, 1573 (Fed. Cir. 1986) (citing Peters v. Active Mfg. Co., 129 U.S. 530, 537 (1889)). The mere addition of other elements, beyond what is claimed, does not avoid infringement – unless the addition of the other elements somehow so alters one or more of the claimed elements so as to make it no longer present in the allegedly infringing process or product. (See Exxon Chemical Patents, Inc. v. Lubrizol Corp., 77 F.3d 450 (Fed. Cir. 1996)).

Courts may also find infringement under the doctrine of equivalents (DOE) if the differences between what is claimed and the allegedly infringing product are insubstantial. Warner-Jenkinson Co. v. Hilton Davis Chemical, Inc., 520 U.S. 17 (1997)). But, under the "all elements rule," a court conducting a DOE analysis must not completely eviscerate any limitation in the claim. (Id.). In addition, the reach of the DOE is limited by the doctrine of prosecution history estoppel (PHE). Under PHE, a patentee may be estopped from expanding the reach of a claim beyond its literal scope where the claim was limited during prosecution for reasons relating to patentability. (Id.). Infringement under DOE is a question of fact, but limitations on DOE, such as PHE and the all elements rule are questions of law.

(b) Indirect Infringement, Importing, and Exporting

In addition to being able to exclude those who directly infringe a patent, the Patent Act allows patentees to exclude those who indirectly infringe under certain circumstances. Patentees may exclude those who induce another to directly infringe, such as by providing raw materials combined with instructions on how to do acts that would be infringing. (See 35 USC § 271(b)). Patentees may also exclude those who contribute to another's direct infringement, such as by providing unassembled pieces of a patented invention that are not otherwise staple articles of commerce. (See 35 USC § 271(c)). Both forms of indirect infringement require proof of some level of intent, or knowledge, on the part of the defendant.

While national borders limit patents geographically, a patentee may exclude others from doing what would essentially be inducement of infringement or contributory infringement except for the fact that the act of direct infringement occurs outside of the country. (See 35 USC § 271(f)). A patentee may also exclude others from importing a patented invention. (See 35 USC § 271(g)).

These rights of the patent grant are quite substantial, and face only a few limitations, which are themselves rather limited. The most significant of the limitations of the patent grant are discussed below.

(c) Misuse, Antitrust, Etc.

For many years before the '52 Act, patentee's were severely limited in the exercise of the rights to sue or license those who induced or contributed to infringement by the too-often applied doctrine of patent misuse, which stemmed largely from then-existing antitrust principles. In addition to the introduction of nonobviousness as an objective standard for patentability, the '52 Act also was expressly drafted to revive the doctrines of contributory and inducement of infringement and to limit the doctrine of patent misuse. (See 35 USC § 271(b), (c), and (d)). As the Supreme Court expressly recognized in an important case written about the same time as the statutory subject matter cases and by the same majority in those cases, the '52 Act "did include

significant substantive changes, and . . . § 271 was one of them." (Dawson Chemical v. Rohn and Haas, 448 U.S. 176 (1980) (Blackmun, J)). Section 271 set forth express provisions for direct, induced, and contributory infringement as well as an express provision that effectively allowed a patentee to elect to sue, license, or even restrictively license anyone otherwise guilty of direct or indirect infringement without committing patent misuse. (See 35 USC § 271(d)).

Today, the limitation on misuse remains strong. And impermissive use of patents is cabined by other areas of law – such as the Rule 11, Fed. R. Civ. P., and antitrust. Attempts to enforce a fraudulently procured patent may be a Sherman Act § 2 violation if the other elements, such as market power, can be proven. (See Walker Process v. Food Machinery Corp., 382 U.S. 172 (1965)). Knowingly suing for infringement over an invalid patent might have given rise to an antitrust counterclaim earlier. (See Handguards, Inc. v. Ethicon, Inc., 601 F.2d 986 (9th Cir. 1979)). Today, in essence, cases raising these issues are analyzed under the Supreme Court's sham litigation test set forth in Professional Real Estate Investors v. Columbia Pictures Indus., Inc., 508 U.S. 49 (1993), which has both an objective prong and a subjective prong. The Court will first look to determine whether the litigation is objectively baseless, and only if it is will the court look to determine whether the plaintiff himself had subjective bad intent.

(d) First Sale, Implied License, Repair & Reconstruction

The doctrine of first sale is another doctrine that may operate to limit the rights of a patentee. Under this doctrine, a patentee's unrestricted voluntary introduction of a patented article into commerce, such as through a sale, may prevent the patentee from exercising his right to exclude others from the particular article so introduced. For example, under this doctrine, a patentee who makes an unrestricted sale of a patented widget may not be able to sue the buyer, or any other downstream user of that particular widget for infringement. After all, the buyer presumably paid the patentee not only for title to the good in the sales sense, but also for permission to use it for its intended purpose. Thus, the first sale doctrine can be viewed as a contract-based doctrine that implies into contracts for unrestricted sales of patented articles a term that

conveys some authority to use the article free from a suit for infringement. But this doctrine really only provides a default rule, because courts have recognized that restrictive terms in a sale – such as a sale accompanied by a promise to make only a single use of the patented article – will be enforceable as long as they do not violate some other rule of positive law, is not ahesionary, or unconscionable. (See Mallinkrodt v Medipart, 976 F.2d 700 (Fed. Cir. 1992)).

A related doctrine is the doctrine of implied license. This is an equitable doctrine governing certain forms of estoppel that steps in to bar a patentee from asserting a right that otherwise does exist. Under a legal estoppel analysis, a license may be implied where a patentee has licensed or assigned a right, received consideration, and then sought to derogate from that right granted. See Wang Labs v. Mitsubishi Electronics, 103 F.3d 1571 (Fed. Cir. 1997)). Under an equitable estoppel analysis, a license may be implied by where conduct by a patentee leads another to act in reliance on that conduct in such a way that it would be unjust to allow the patentee to exclude the actions taken in reliance. (See, e.g., Met-Coil Systems Corp. v. Korners Unlimited Inc., 803 F.2d 684 (Fed. Cir. 1986)).

Another related doctrine is the repair/reconstruction doctrine. The theory of permissible repair versus impermissible reconstruction is really a corollary to the first sale doctrine. Under the first sale doctrine, a buyer in an unrestricted sale from the patentee may be given authority to use and even resell the patented article. The repair/reconstruction doctrine further unpacks the details of such an unrestricted sale and also gives the buyer repair the article as part of his right to use and sell it, but does not give him a right to rebuilt the article once it is worn out. The difference between permissible repair and impermissible reconstruction is very difficult to determine and may require some type of all-things-considered analysis. (See Sandvik Aktiebolag v. E.J. Company, 121 F.3d 669 (Fed. Cir. 1997)).

(e) Experimental Use and the Hatch-Waxman Act

Some commentators have long suggested that patent law may permit non-commercial, experimental use of a patented invention as an exception to infringement under a so-called experimental use exception. To the extent this doctrine exists, it was severely limited in the case of Roche Products, Inc., v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 1984), in which the court held that limited experimental use by a generic drug company to obtain Food and Drug Administration (FDA) approval for use after the patent expired was an infringing use. Congress responded to Roche with the enactment of the Hatch-Waxman Act in 1984, which added Section 271(e) to the Patent Act, and which essentially deems activities reasonably related to FDA approval to be non-infringing, so as to streamline FDA approval of so-called Abbreviated New Drug Applciations (ANDA's). At the same time, the Act requires the sponsor of the ANDA to make a certification that the drug will not infringe any valid claim and deems the filing of such a certification to be a jurisdictionally-creating act of infringement so that a patentee can bring suit on the patent during the FDA approval process and if victorious, keep the competition from coming to market until after the patent expires. At the same time, the competition is allowed to make progress on obtaining FDA approval before expiration of the patent so that he is ready to come to market soon after expiration. Thus, in the field of biotechnology, the experimental use exception may be viewed as rather liberal, but restrained by the mechanisms of the Hatch-Waxman Act and in other fields of technology the exception is very limited by the holding of Roche, if it exists at all.

(f) Government Infringement

Finally, the federal and state governments are protected from infringement by the doctrine of sovereign immunity. The Federal Government has made a limited waiver of sovereign immunity and will allow a patentee to sue in the United States Court of Claims for "his reasonable and entire compensation." (28 USC § 1498). Recently, the Supreme Court decided that state governments were immune from suit for patent infringement and that Congressional efforts to abrogate that immunity were

unconstitutional under the 11th Amendment. (See Florida Prepaid Postsecondary Education Expense Board, v. College Savings Bank, 527 U.S. 627 (1999)).

(g) Other Tools for Liability Rule Treatment

The high costs of litigation under the present rules of civil procedure combine with the ability for an infringer to be kept effectively judgment proof through corporate and bankruptcy laws to create a type of liability rule treatment for any patent. That is, so long as an infringer respects the formalities of corporate law and bankruptcy law, the infringer will be able to pay its employees and other creditors up to the time when the court enforces a judgment of infringement remedies. The litigation costs may even be high enough to prevent the patentee from seeking court intervention in the first place, and in the least the litigation process will typically take several years.

4. Remedies for Patent Infringement

Patents are particularly powerful tools because of the strong remedies that are available for patent infringement. The victorious patentee in an infringement suit will be awarded damages "adequate to compensate for the infringement, but in no event less than a reasonable royalty." (35 USC § 284). If the patentee can prove them by a preponderance of the evidence, a patentee may be awarded lost profits, which may include lost profits on the sales of products covered by the patent, and perhaps other products sold together with such covered products, as well as losses due to price erosion. (See Panduit Corp. v. Stahlin Bros. Fibre Works, 575 F.2d 1152 (6th Cir. 1978)). The patentee may also receive enhanced damages for willfulness, which is a question of fact to be proven by clear and convincing evidence, and if found by fact-finder, then it is within the judge's discretion to treble damages and award attorney fees. (35 USC §§ 284-85).

The ability for patentees to obtain enhanced damages for willfulness may have been significantly curtailed recently by the Federal Circuit decision in Seagate. (See In re Seagate Technology, LLC, 497 F.3d 1360 (Fed. Cir. 2007) (en banc)). In Seagate, the Federal Circuit seemed to have held that proof of willful patent infringement at least

requires a showing of objective recklessness; that there is no affirmative obligation to obtain an opinion of counsel in order to oppose a claim of willful patent infringement; and that patentees must now show by clear and convincing evidence that the infringer acted despite objectively high likelihood that its actions constituted infringement of valid patent to establish willful infringement. The court also held that the assertion of advice of counsel defense and the disclosure of opinions from opinion counsel does not constitute a waiver of the attorney-client privilege or the product immunity for communications with trial counsel.

In addition, the heart of the right to exclude is the patentee's right to receive an injunction, and permanent injunctions almost always were awarded to patentees who won infringement suits until very recently. (See 35 USC § 283). The recent Supreme Court decision in eBay may weaken this long-standing practice. (See eBay Inc. v. MercExchange, LLC, 126 S.Ct. 1837 (2006). Some see this case as having raised the bar for patentees seeking an injunction after there has been a full adjudication of patent validity and infringement by injecting more discretion in the determination of essentially whether an injunction is in the broadly defined public interest. Others see the case as merely restating the established practice that an injunction should issue once validity and infringement have been decided in court. In the final analysis, the full impact of the eBay case remains an open question for debate.

In the case of preliminary injunctions, irreparable harm is often presumed for patents, if the patentee can show a likelihood of success on the merits, which requires the patentee to show that the patent in suit is valid and infringed. (See Smith Int'l. Inc. v. Hughes Tool Co., 718 F.2d 1573 (Fed. Cir. 1983)). The presumption of validity, alone, is not sufficient to make this showing.

D. Inventorship and Ownership

As with the contracting over any asset, the first issue to be determined when contracting over a patent is initial ownership. Ownership of a patent in the first instance is tied to

inventorship. This practice is somewhat unique for the US, because other countries allow ownership to be initially vested more directly in the inventor's employer.

Generally, only the actual inventor or inventors may file a patent application, unless the inventor is dead, incapacitated, or if certain conditions satisfied when the inventor is otherwise unavailable. (35 USC §§ 111, 117, 118). Because inventorship is a legal status that either exists or does not exist based on objective facts and regardless of intent, the possibility of joint inventorship must often be considered. Joint inventorship will not be prevented merely because all inventors did not physically work together or at the same time, each did not make the same type or amount of contribution, or each did not contribute to every claim in the patent; and all that is required is that each joint inventor contributed in a significant manner to the conception or reduction to practice of the claimed invention. (35 USC § 116; Pannu v. Iolab Corp., 155 F.3d 1344 (Fed. Cir. 1998)).

Joint inventorship is can have at least two significant impacts on the value of a patent to a perspective assignee or licensee. First, the misnaming of inventors can invalidate a patent unless it is done without deceptive intent, in which case it may be corrected. (35 USC §§ 116, 256). Second, joint inventors are joint owners, and in "the absence of any agreement to the contrary, each of the joint owners of a patent" may exercise or assign or license the patent rights "without the consent of or accounting to the other owners." (35 USC § 262). Thus, any perspective assignee or licensee of a patent must wary of paying any price for an assignment or license unless certain to be contracting with the sole owner of the patent (sole inventor, assignee of sole inventor, or assignee of all inventors) because the presence of any other joint inventor could render the patent invalid or dissipate the entire value of the patent assignment or license by freely licensing any competitor of that perspective assignee or licensee.

E. Patent Assignments and Licenses

The rule that the inventor is the owner of the patent is only a default rule and others may develop rights in a patent by express contract language, by contracts implied in law and

in fact, by quasi contract, or by estoppel. For example, employers often assert various contractual rights to the inventions of their employees. The default rule is that the individual inventor owns the rights to a patent for an invention developed while in someone else's employ. To be sure, an express contract to the contrary will require a contrary result. Furthermore, under the "employed to invent" doctrine, even absent express contract language, an employee who is hired or later directed to solve a specific problem or to exercise her inventive faculties may be considered to have contractually assigned to her employer her rights in any inventions she makes in discharging such obligations. (See, e.g., Standard Parts Co. v. Peck, 264 U.S. 52 (1924)). In addition, under the "shop right" doctrine, an employee who uses his employer's resources to conceive or reduce to practice a patented invention may be found to have given her employer at least some limited, non transferable, non-exclusive, royalty free license to use the invention. Shop rights may arise under various legal or equitable theories: an implied in fact license, such as where the behavior of the parties implies the existence of a license (see McClurg v. Kingsland, 42 U.S. 202 (1843)); estoppel, such as where the employee participates in the installation of an embodiment of the patented invention in the employer's business without informing the employer of the patent rights or demanding payment (see Gill v. United States, 87 U.S. 517 (1896)); or some general notion of equity or fairness, such as where the employee uses the employer's resources to develop the invention (see United States v. Dubilier Condenser Corp., 289 U.S. 178 (1933)). Because the employed to invent and shop right doctrines ultimately arise out of employment relations that are governed largely by state contract and employment laws, the particular laws of each relevant state must always be considered; and, indeed, a number of states have passed so-called inventor-protection statutes designed ensure that express contractual language is used before an employee's rights in her invention will pass to her employer.

Ownership of patents also presents issues outside of the employment relationship and to facilitate transactions over title to patents, the Patent Act does have its own recording statute. (35 USC § 261). Like under most recording statutes, a bona fide purchaser for

value cuts off the rights of a prior owner who has failed to record to the prior assignment in the PTO. Both patents and patent applications can be assigned, (see 35 USC § 261) and it is ordinary practice for owners of both to record their interests with the PTO assignments branch. Indeed, exclusive licensees often will record their interests as well. The goal of anyone asserting an ownership-type interest in a patent should be to put the rest of the world on at least constructive notice of that interest to prevent it from being cut off by operation of the recording statute. This goal can be achieved by filing in accordance with that statute.

Finally, ownership of a patented article does not give ownership of the patent. However, under the so-called first-sale doctrine, a purchaser of a patented article from a patentee does have a limited license to use, sell, and even repair, but not reconstruct, that particular article. Patentees may restrict this right further through express contract language, such as a single-use only restriction, as long as that restriction does not violate some other rule of positive law, is not ahesionary, or unconscionable. (See Mallinkrodt v Medipart, 976 F.2d 700 (Fed. Cir. 1992)).

As already mentioned, the credible threat of a suit for patent infringement is absolutely necessary to the value of a patent. Thus, the rules on who can bring suit and who must be joined in such a suit must inform the structure of any prudent transaction over a patent.

The default rule for assignors is that once a patent owner transfers all interests in the patent to another, she no longer has standing to sue for any post-assignment infringement. However, an assignor may wish to retain some right to sue future infringers if the price paid for the assignment is to be paid over time by the assignee. In such a case, the assignor must retain the right to sue and must commit the assignee to joining in the suit; and courts will essentially treat the assignment like an exclusive license. (See Grantham v. McGraw-Edison Co., F.2d (7th Cir. 1971)).

In contrast, the assignee has title ownership of the patent and therefore as expected does have standing to sue for post-assignment infringements for so long as title is held.

In addition, the assignee may have standing to sue for pre-assignment infringements if the assignor specifically conveys such a right to sue. (See Arachnid, Inc. v. Merit Indus. Inc., 939 F.2d 1574 (Fed. Cir. 1991)).

An exclusive licensee generally has standing to sue for infringement within the area and time of exclusivity. But, while the exclusive licensee has standing, she will most likely have to join the patent owner as a necessary or indispensable party. (See Rule 19, Fed. R. Civ. P.; see also Provident Tradesmen's Bank & Trust Co. v. Patterson, 390 U.S. 102 (1968)). Similarly, a patentee may also be required to join exclusive licensees. (Id.). In contrast, a nonexclusive licensee generally does not have standing to sue for infringement. (See Waterman v. McKenzie, 138 U.S. 252 (1891)). The key to standing is some proprietary interest in the patent. Thus, courts have held that a "contractual provision providing a licensee with a right to sue cannot confer that licensee a right to sue under patent laws where there is no such right under patent laws." (Ortho Pharm. Corp. v. Genetics Institute, Inc., 52 F.3d 1026 (Fed. Cir. 1995)).

Under the Supreme Court's decision in Lear v. Adkins, a party to a patent license or assignment will not be prevented by either estoppel or even express contractual agreement from contesting the validity of the patent as a defense to a suit for infringement or breach of the license or assignment contract. (Lear v. Adkins, 395 U.S. 653 (1969); see also Beckman Instruments, Inc. v. Technical Dev. Corp., 433 F.2d 55 (7th Cir. 1970) (Lear applies to exclusive licensees); Bull v. LogEtronics, Inc., 323 F. Supp. 115 (E.D. Va. 1971) (Lear applies to assignees)). The general rule of Lear has been interpreted to require a challenger to do more than simply stop paying the assignment or licensing royalties or other fees, and must instead actually challenge validity. (See, e.g., Rite-Nail Packaging Corp. v. Berryfast, Inc., 706 F.2d 933 (9th Cir. 1983)). The recent Supreme Court decision in Meddimmune makes it particularly easy for the licensee to bring this challenge because he no longer needs to breach the license contract itself and may even be able to keep the patentee bound by its other terms. (See See MedImmune, Inc. v. Genentech, Inc., 127 S.Ct. 764 (2007)).

In contrast to the Lear doctrine, which impacts licensees, the assignor of a patent is estopped from challenging validity. Assignor estoppel makes sense because otherwise the assignor would be allowed to challenge the very rights he sold. (See Diamond Scientific Co. v. Ambico, Inc., 848 F.2d 1220 (Fed. Cir. 1988)).

III. Legal Practice

A. Enforcement & Court Structure

Although the state and federal court systems in the US function in similar ways, commercial parties often prefer the federal courts because the state courts are often seen as being primarily occupied with social and criminal matters, while the federal courts are generally seen as being more adept at handling commercial matters. But the federal courts are courts of limited jurisdiction and there are only two primary bases for jurisdiction in federal court. The first, called federal question jurisdiction and governed by 28 USC § 1331, allows access to the federal courts when the well-pleaded complaint states issues that arise under federal law. The second, called diversity jurisdiction and governed by 28 USC § 1332, allows access to the federal courts when no defendant in the case is a citizen of the same state as any plaintiff and the amount in controversy exceeds $75,000. Once a case is properly before a court, either state or federal, it generally will be possible for the court to exert supplemental jurisdiction over all of the issues in the same case, whether each of those matters arises under state or federal law.

The federal trial courts in the US are called district courts. For commercial cases in these courts, it is common for the process to take 3-5 years and cost $3-5 million in legal fees. In complex cases, it is not rare for the legal fees to reach well over $1-2 million per month.

The bulk of the time and money in these cases is spent in the process leading up to the actual trial, in the process called discovery. The Federal Rules of Civil Procedure allow the parties to request from each other through discovery vast amounts of information

that then essentially must be provided in response. In commercial cases, discovery often involves the exchange of millions of pages of documents detailing all sorts of information relevant to the suit including business records, letters sent and received, emails, etc. Discovery also typically includes depositions, which are official proceedings conducted under the power of the court and recorded by transcript and often by video, during which a witness is asked questions and required to provide truthful answers. The witness may be from a party to the suit or from a third party. In addition, discovery also can include opportunities for the joint inspection of key facilities, such as factories, labs, etc.

It is common for discovery to reveal information that is considered to be confidential and courts routinely enter an order requiring each side to maintain as secret the confidential information it receives from the other side. Often, for example, the court will require the information to be provided, but only to the lawyers who work for the outside law firm that is representing the opposing side, and will then require that those lawyers not share the other side's confidential information with the lawyers and business people who work within their own client's business.

The central significant limit that protects some information from being revealed through the discovery process is the attorney-client privilege and the related work-product immunity. The attorney-client privilege is very strongly respected in the US courts and generally will allow parties to withhold from discovery those communications that are between an attorney and a client and contain legal advice. The work-product immunity generally will allow parties to withhold from discovery information that was generated in anticipation or preparation for litigation. A central exception to both of these limits on discoverability of information is when the actual information sought to be withheld is important to deciding an issue in the case, such as whether a client actually acted on the well reasoned advice of counsel. Most courts will require parties to maintain and produce a log of all documents that the party seeks to withhold from discovery and to provide a brief description on the log of the document including for example who wrote it, when it was written, to whom it was written, in which file it was stored, and the reason

for withholding it. Trial judges often hold hearings, often confidentially and only involving the outside counsel for the parties, to adjudicate whether particular information is properly subject to being withheld from discovery.

Trials in commercial cases in the federal system typically take several trial days, which are sometimes contiguous but sometimes spread over a few weeks. The Sixth Amendment of the Constitution provides that in most cases that involve the potential awarding of a remedy like damages, as opposed to only an injunction, both sides in the case will have a right to have a jury, as well as a judge. It is common in these cases for at least one side to request a jury and once such a request is made the jury will almost always be provided. When a jury is present, the jury will decide the questions of fact, while the judge will decide the questions of law.

B. Alternative Dispute Resolution

Both courts and practitioners in the US are generally in favor of dispute resolution techniques that are alternative to litigation. The two central candidates for such alternative dispute resolution (ADR) techniques are arbitration and mediation.

In arbitration, a neutral person or persons is brought in to reach a decision and the decision is generally seen as binding on the parties to the dispute.

In mediation, the neutral is only allowed to help broker an agreement between the parties, and is generally not encouraged or empowered to reach any decision. While courts often have limited jurisdiction and limited tools available as remedies, the parties can essentially agree as between themselves to structure their settlement in whatever way they like. As a result, mediation often allows for more flexibility. In addition, because mediation usually is less adversarial than litigation, it also can help build or maintain a positive working relationship between the parties.

One difference between litigation and most forms of ADR is that the parties to the dispute maintain more control over the dispute in ADR than in litigation. Litigation gives power to the courts to control the dispute. Included in this control is the selection of the

neutral person or people. In ADR, the parties often take great care to ensure that the neutral has particular experience and training in particular areas of law, business, or technology. Similarly, ADR proceedings usually are not official public proceedings like court actions and so can be more effective in keeping matters private and confidential.

A second difference is the demand on resources. ADR proceedings generally cost significantly less and take significantly less time than full litigation proceedings. Indeed, it often is easier to enforce the results of ADR proceedings in foreign countries than it is to enforce litigation results.

C. Contract Implications from Treatment of Intellectual Property in Bankruptcy

The issues raised by bankruptcy can be particularly difficult in connection with intellectual property assets because a key value for intellectual property assets is the credible threat of a serious enforcement lawsuit. Under the basic procedures of bankruptcy law, the filing of a bankruptcy petition has two basic legal effects: (1) it creates a bankruptcy estate, containing roughly of all of the debtor's interests in property (see 11 USC § 541); and (2) it automatically stays all actions against the debtor, and anyone wishing to proceed thereafter against the debtor must go through the bankruptcy court (see 11 USC § 362).

One bankruptcy issue that is particularly acute for intellectual property assets is the potential difficulty in obtaining prompt action on any assets in a bankruptcy estate. As mentioned frequently throughout this course, the entire value of an intellectual property asset is the credible threat of an injunction. Any uncertainty or delay in the ability to obtain this injunction can dissipate the credibility of the threat.

More specifically, in the case of a relatively short-lived intellectual property right such as a patent, it can dissipate the entire right itself. These concerns may motivate those structuring intellectual property based transactions so as to decrease the likelihood that any ownership or significant license interest in the asset is held by the party most likely to find itself in bankruptcy voluntarily or involuntarily. Indeed, a common strategy is to

create a separate intellectual property holding company that will give licenses to one or all of the parties in the transaction.

Similarly, in the case of a trademark license, where ongoing quality control is essential to the maintenance of the mark, uncertainty and delay may undermine the ability to control quality, thereby leading to destruction of the mark. To protect the mark, the trademark licensor may move the bankruptcy court to compel the debtor to either fully assume or reject the license agreement. (See 11 USC § 365(d)). Alternatively, the trademark owner may move the court to lift the automatic bankruptcy stay, "for cause," which includes "lack of adequate protection of an interest in property of such party in interest." (See 11 USC § 365(d)(1)).

A second bankruptcy issue that arises around intellectual property assets stems from the tendency of many intellectual property-based contracts to form the basis of on-going contractual relationships, such as contracts with ongoing royalty payment or quality control provisions. Such contracts for which some performance remains due are called "executory contracts," and are the subject of particular bankruptcy laws. Subject to court approval and certain other conditions, the debtor in bankruptcy may elect to assume, assume and assign, or reject an executory contract. (See 11 USC § 365). If the debtor rejects the contract, the other party simply becomes one of the general unsecured creditors of the bankruptcy estate. (See 11 USC § 365(g)). Specific performance is not a remedy available to the other party to the contract, even if it would have been available outside of bankruptcy. (See Lubrizol Enterprises, Inc., v. Richmond Metal Finishers Inc., 756 F.2d 1043 (4th Cir. 1985). In addition, a creditor-licensee may retain certain licensed rights under an intellectual property license even if the debtor-licensor elects to reject the other provisions of the license agreement. (See 11 USC § 365(n)).

D. Ethical Considerations in Contracting over Intellectual Property

The generally applicable rules of professional responsibility have several specific implications for the lawyer engaged in contracting over intellectual property. The

materials in this section discuss some of the most important of these issues, and do so in the context of the American Bar Association's Model Rules of Professional Conduct, as amended through 1997 ("Model Rules"). Although these model rules are largely in accord with the rules applicable in most states, the applicable rules do vary across the states and the practitioner is cautioned to follow those applicable in each pertinent state.

Every lawyer has a duty to provide competent legal services. (See Model Rule 1.1). Facility with industry-specific business issues, technology, and the applicable substantive intellectual property law may be important prerequisites to the ability to provide competent legal services in the area of intellectual property contracts. This facility may be gained through experience, or the use of experienced co-counsel. In certain cases, the limited scope of the attorney's involvement may alleviate the need for some of this specialized expertise. (See Model Rule 1.2). A related issue is that the attorney must be licensed to practice in each state that might consider the representation involved to constitute practicing law within that state. (See Birbrower v. Superior Court of Santa Clara County, 17 Cal. 4th 119, 919 P.2d 1 (1998).

Negotiations over intellectual property contracts may also raise ethical issues concerning direct communications between a lawyer and the counterpart to the lawyer's client. A lawyer must not communicate about the subject of the lawyer's representation directly with a person the lawyer knows to be represented by another lawyer in the matter, absent consent of the other lawyer or some other authorization. (See Model Rule 4.2). Where the other party is a business entity, this rule extends to its officers, directors and, managing agents, and partners in the case of a partnership. If the other party is not represented in the matter by a lawyer, the lawyer must not give advice to that party other than the advice to obtain counsel. (See Model Rule 4.3). Whether the other party is represented by counsel or not, the lawyer must not make a false statement of material fact or law to that party. (See Model Rule 4.1).

Particularly in smaller transactions the lawyer must also be careful to avoid conflicts of interest as well as excessive participation in the business of one or both parties. It may be unethical for a lawyer to represent both parties to a contract, even when they have

expressly consented to representation by a single lawyer. (See Model Rule 1.7). Generally, the issues to consider are the level of potential conflict and the possibility that the lawyer's representation of either of the parties will be adversely affected. For example, the Official Comment to Model Rule 1.7 provides that joint representation is not appropriate if the parties interests "are fundamentally antagonistic to each other, but common representation is permissible where the clients are generally aligned in interest even though there is some difference of interest among them." A lawyer should only accept consent for joint representation after careful disclosure of the existence and nature of the conflict including possible adverse consequences. To be sure, lawyers within the same firm are considered to be "one lawyer." (See Model Rule 1.1). An effort to have the lawyer serve as an intermediary will not avoid these ethical issues; and, in practice, is unlikely to be structured in a way that would satisfy the more stringent rules for such an approach. (See Model Rule 2.2). Lastly, if the lawyer agrees to accept participation in the client's business as compensation for the legal services, then the terms of such compensation must be fair and reasonable, the client must be given an opportunity to seek the advice of independent counsel, and the client must give written consent. (See Model Rule 1.8(a)).

IV. Public Intervention

There is a substantial role for the public in the R&D process in the US. A great deal of public funding is made available to support basic research at academic organizations and a great deal of public funding is made available to support development work at private business.

Under the Bayh-Dole Act, when publicly funded research leads to patentable inventions, the inventors are encouraged to seek a private patent. The Act was designed to increase the downstream development, or commercialization, of new technologies. And many see it as having made a great positive contribution to the process of invention development and deployment.

Often there are public policy oriented questions about what kind of special access rights the public may receive to inventions that are derived from public funding. In the US, it is important to always remember that the national government can always in effect take for use by itself or by anyone it elects, a license to any patent, leaving the patentee only the right to bring a suit to obtain from the government just compensation for this taking. In addition to this general mechanism, when the government has funded the research that underlies the patent, the Government also may under certain circumstances exercise special “march-in” rights under the Bayh-Dole Act for research funded by the government and conducted outside the government or under the Stevenson-Wydler Act for research funded by the government and conducted inside the government. Although not often exercised, these special “march-in” rights enable the Government to require the patentee to give some third party a license to the patented technology.

Some have feared that the patenting of such basic scientific discoveries would lead to a decrease in the rate of downstream science because of the feared need for countless license negotiations. Yet, despite there being many patents in basic science, having many diverse owners, there is no evidence that a significant number of scientists get held up by the need for patent permissions. Many are given express permission for free and many others are in effect given free permission because the patents are not enforced against them. On other occasions, licensing arrangements are successfully negotiated. As canvassed in a 2006 review article by Cauffield et al. in the journal Nature Biotechnology, the empirical data shows that patents do not block science. (See Timothy Caulfield, Robert M. Cook-Deegan, F. Scott Kieff, & John P. Walsh, Evidence And Anecdotes: An Analysis Of Human Gene Patenting Controversies, 24 Nature Biotechnology 1091 (2006)).

V. Conclusion

Generally, trade secret, contract, and patent rights in the US are enforceable in relatively predictable ways. Recent shifts in views about patent policy at the national level may have injected increased uncertainty into the patent system itself, as well as

into these other areas of law. Only time will tell the exact extent of this impact. In general, R&D cooperations are relatively attractive investments in the US, for those who reside in the US as well as those who reside elsewhere.