

Rules and Regulations For Playing the Game.

Patential™

PRESCRIPTION FOR SUCCESS

OVERVIEW AND BACKGROUND

This is a game about securing the right to develop drug inventions, and making money from such development. There are drugs for treatment of different diseases, such as cancer and diabetes. Each player has the opportunity to obtain a PATENT on each invention. Having a PATENT may significantly increase the income or revenue obtained from selling that drug. However, before any drug can be sold, the Food and Drug Administration (FDA) must provide its approval. This approval is obtained by having human volunteers take the drug to prove it is safe and works to treat the disease. At that point, drug sales can commence.

It will cost money to obtain a PATENT. Because of the large costs associated with human trials, it will cost even more to get the FDA to approve the drug for sale. In addition, payments will need to be made to the inventor. The game is about making the right choices for the right drugs as to when to get a PATENT, when to develop another drug and when to compete with others in drug sales.

Funds collected through rolls of the money die reflect the player's ability to raise funds from "angel" investors (who tend to provide lower amounts of investment) and venture capitalists (who are willing to provide more money). This money can be used for any purpose.

At the start of each turn, each player must decide whether to take on the burden of developing another drug. The decision will make a significant difference to cash flow and drug flow. It costs a lot of money to get the drug to the revenue stage, but if players don't develop drugs, revenue will not be earned. These issues must be carefully balanced.

CONTENTS

- 1 six-sided money die, with 1 (\$1,000,000), 2 (\$2,000,000) and 3 (\$3,000,000) annotations.
- 1 regular six-sided die.
- 18 double-sided INVENTION CARDS (Licensed/Bought).
- 18 corresponding double-sided INVENTION PIECES (Patented/Not Patented).
- 4 (sets of 3) colored stands to hold INVENTION PIECES; one set for each Player
- Money in 7 denominations
- A game board with labeled squares and spaces.
- Quick-start rules.

PREPARING THE GAME

- Shuffle INVENTION CARDS.
- Place INVENTION CARDS on the corresponding part of the board.
- Place the money and INVENTION PIECES so that all players can reach them.
- Each player takes 3 colored stands of one color
- POTENTIAL can be played with one to four players, but is best played with two to four players. The game takes about 30 minutes per player. For example, it takes approx. 60 – 90 minutes with two players (but may take longer for the first couple of games).
- POTENTIAL is designed for ages 12 and up.
- To begin play, each player rolls the regular die. The player rolling the highest number goes first.
- If game is not played with COMPETITORS, any reference to COMPETITORS below can be ignored.

PLAYING THE GAME

Before each turn, roll money die and place appropriate amount in front of player.

- 1 is \$1,000,000
- 2 is \$2,000,000
- 3 is \$3,000,000

1. SECURING RIGHTS TO INVENTIONS:

- Before each turn, a player has the option to buy or license the rights to one (and only one) INVENTION CARD. Each player cannot have more than three CARDS at any given time.
- If a player has less than three INVENTION CARDS and chooses to take another, that player picks up the top INVENTION CARD.
- If that player has sufficient money, he or she can pay the license amount or buy the CARD outright for the amount stated on the CARD.
- The CARDS are two-sided, to show whether the invention has been bought outright or licensed.
- The player turns the card to the corresponding side and lays it in front of him or her.
- Buying the invention outright is expensive, but means that no other "fees" are due in the future.
- The player then places the corresponding INVENTION PIECE, color-coded to match each CARD, on TAKE INVENTION CARD, which is the starting point of the game. Each PIECE is two-sided. One side is marked PATENT. All PIECES start with the PATENT side down in the player's colored stand.
- The player may then pay \$100,000 and move the PIECE to either the APPLY FOR PATENT or ENTER CLINICAL TRIAL square.

If the player decides not to pay for the CARD, he or she must return the CARD to the top or bottom of the stack of INVENTION CARDS.

INVENTION CARDS

- Each card is two-sided and states the type of drug invention, (i.e.: cancer, arthritis, Alzheimer's, cardiac, infectious disease and diabetes).
- There are three types (1, 2, and 3) for each invention.
- The cost to buy the CARD outright (and thus not be liable for any other payments stated on the CARD in the future) and the cost to buy a license is stated.
- If only a license is bought, each of the fees noted on the CARD must be paid when appropriate.
- Fees are paid when the PIECE lands on squares labeled FILE IND, ENTER PHASE 1, ENTER PHASE 2, ENTER PHASE 3 and NDA APPROVED, respectively. Fees are also paid for Royalties on certain squares.
- If a PIECE is sent back to any of those squares during the game, players do not have to pay those fees again. However, if a player voluntarily returns a PIECE to those squares again, the fees must be paid.

The following is one example of such an INVENTION CARD:

The card is for a Cancer treatment. It costs \$3,000,000 to buy the invention outright, or \$100,000 to license it. If bought outright, the player need only pay the regular fees due, e.g., on ENTER PHASE 1 just \$1,000,000. If the card is licensed, an extra fee is due, namely, \$100,000 for IND, \$100,000 for PHASE 1, \$300,000 for PHASE 2, \$500,000 for PHASE 3, \$500,000 for NDA and \$500,000 for ROYALTIES. The revenue to be received from the invention is \$18,000,000 when patented and \$3,000,000 when not patented i.e., generic.

Cancer 1	Buy Invention	\$3,000,000
	Buy License	\$100,000
	Royalty Payment	\$500,000
	IND	\$100,000
	Phase 1	\$100,000
	Phase 2	\$300,000
	Phase 3	\$500,000
	NDA	\$500,000
Revenue when Patented		\$18,000,000
Revenue as Generic		\$3,000,000

Cancer 1	Buy Invention	\$3,000,000
	Buy License	\$0
	Royalty Payment	\$0
	IND	\$0
	Phase 1	\$0
	Phase 2	\$0
	Phase 3	\$0
	NDA	\$0
Revenue when Patented		\$18,000,000
Revenue as Generic		\$3,000,000

2. ABANDONING AN INVENTION

At the start of any turn, a player may decide to abandon one or more inventions and return the INVENTION CARDS to the bottom of the pile of CARDS and remove the PIECES from the board. That player may then license or purchase another INVENTION CARD (including one that was just abandoned if the player is trying to become a COMPETITOR as described below).

3. PIECE MOVEMENT

- Each turn, each player has the option to roll the regular die to move each of that player's PIECES around the BOARD.
- Once the die is rolled, the player must move each PIECE on the BOARD the corresponding number of squares.
- PIECES must stop at each square with the stop sign icon, regardless of the number on the die.
- Players must then follow the instructions on the square on which the PIECE has landed.
- Any and all fees must be paid as soon as a PIECE lands on any given square.
- If the player decides not to pay the fee, that PIECE must be removed from the board and the INVENTION CARD returned to the bottom of the stack of INVENTION CARDS.

4. GETTING A PATENT

- On one portion of the board, a player can get a PATENT on each INVENTION and turn his or her INVENTION PIECE over to the PATENT side. This will significantly increase the revenue that he or she may obtain in the DRUG SALES part of the game.
- A player may abandon the patent process at any time at the start of any turn and move to ENTER CLINICAL TRIAL (without getting a patent) before the die is rolled.
- Squares exist where a player can lose a PATENT. If he/she loses the PATENT, he/she will still receive revenue, but only at the generic rate.

At those squares, turn the INVENTION PIECE to the non-PATENT side.

- You can begin the patent process at the start of any turn by moving an INVENTION PIECE, not on its patent side, to the APPLY FOR PATENT square and paying the appropriate fee.

5. APPROVAL TO SELL A DRUG

- Players can move an INVENTION PIECE to the ENTER CLINICAL TRIAL square, from TAKE INVENTION CARD upon payment of the appropriate fee(s).
- From the ENTER CLINICAL TRIAL square, players may move the INVENTION PIECE to FILE IND and then proceed around the board until the PIECE gets to the NDA APPROVED square.

6. COLLECTING REVENUE

- Once a PIECE is NDA APPROVED it is moved to the START DRUG SALES square which is the start of DRUG SALES.
- The PIECE is moved around the DRUG SALES portion of the BOARD until it reaches the DRUG NO LONGER HAS VALUE square.
- When the PIECE reaches the DRUG NO LONGER HAS VALUE square, the PIECE is removed from the board and the INVENTION CARD returned to the bottom of the stack of INVENTION CARDS.
- When a player has an INVENTION PIECE of the same type as another INVENTION PIECE without a patent in DRUG SALES, i.e., on any of the outer squares of the board (from BEGIN DRUG SALES to DRUG NO LONGER HAS VALUE), any revenue is collected at the generic rate for all INVENTION PIECES of that type.

7. COMPETITORS AND LITIGATION

- Once a player has a INVENTION PIECE in DRUG SALES, any other player on his or her turn may try to become a COMPETITOR.
- The COMPETITOR must have an INVENTION PIECE of the same type (e.g., cancer) and the INVENTION PIECE cannot be patented.
- The COMPETITOR may move an unpatented PIECE of the same type to the ENTER CLINICAL TRIAL square.
- Alternatively, that player may buy or license an INVENTION CARD of the same type (even if it is not the next CARD in the pile), pay \$100,000 and move the corresponding INVENTION PIECE to the ENTER CLINICAL TRIAL square.
- If the COMPETITOR moves an unpatented INVENTION PIECE to ENTER CLINICAL TRIAL, the player must then:
 - Pay a fee of \$20,000,000 and move to the NDA-APPROVED square, and;
 - Pay the stated amounts to move to START DRUG SALES
 - This process can be done only one time per turn for each player
- A player having a patented drug, i.e., an INVENTION PIECE with a PATENT on it, in DRUG SALES may sue (litigate) any COMPETITOR in the START DRUG SALES square who does NOT have a PATENT on his/her own drug.
- A player with a PATENT on his/her drug cannot be sued by the other player. Instead, both players collect revenue at the patented rate.

8. LITIGATION

In order to litigate, the following steps are followed:

- When a COMPETITOR places an INVENTION PIECE with no patent on the START DRUG SALES square, the patent owner can choose to pay \$5,000,000.
- The COMPETITOR then pays \$5,000,000 (if he/she wishes to contest the patent) or returns his or her corresponding PIECE to the START/TAKE INVENTION CARD square.
- If both players have paid the \$5,000,000, the patent owner rolls the die.
- If the player rolls one or two, the PATENT(s) is/are lost and the patent owner's INVENTION PIECE(s) is/are turned over to the non-PATENT side, and the other player becomes a COMPETITOR and can continue with sales. Both players are now COMPETITORS and collect REVENUE only at the generic (non-patented) rate.
- If the roll is three, four, five or six, the would-be COMPETITOR's INVENTION PIECE is returned to TAKE INVENTION CARD.

Note: the would-be COMPETITOR may try again on his/her next turn.

9. Buy the Card/Roll for Cards

On these squares, when a player decides to purchase another player's INVENTION CARD, that card is transferred to the purchaser (and remains on the same side, i.e., licensed or bought). In addition, the INVENTION PIECE is placed into one of the purchaser's stands (and remains on the same side, i.e., patented or generic). The PIECE remains on the same square of the board until the purchaser's next turn.

OTHER RULES AND SUGGESTIONS

- Players may make deals at any time on any fair terms with any other player.
- Players should ensure they have sufficient funds before rolling the die, because the consequence of insufficient funds is the loss of the INVENTION CARD and INVENTION PIECE.
- Keep some spare funds around in case of litigation or interference.
- Note that the strategy in the game changes as people get into the DRUG SALES, so prepare for this by holding appropriate funds in advance.
- In one alternative, the players may start with a certain amount of money such as \$5,000,000 or even \$25,000,000.
- When another player is trying to become a competitor, it may be wise to consider settling any lawsuit (before the die is spun) on appropriate terms.
- In another version, players can let others buy whichever INVENTION CARD they desire that is available, not just the one needed to become a COMPETITOR.

WINNING

The winner is the first player to have \$1,000,000,000 on hand at the end of any turn.

GLOSSARY

TERM/PHRASE	DESCRIPTION
ADVERSE REACTION	This refers to a side effect of a drug. Drugs are designed to have a certain beneficial effect, but unfortunately are sometimes found to have an adverse effect. For example, a cancer drug may cause a reduction in size of a tumor (the desired effect) but also cause vomiting. This adverse reaction may or may not be important in determining whether a drug will ultimately be approved. In some cases, adverse reactions are a side effect that can be tolerated, since the drug saves the patient's life. In other cases, the side effect may be eliminated by changing the dosage or manner in which the drug is administered. In other cases, the drug will not be approved for sale.
ALZHEIMER'S	A disease in the brain that causes memory loss and loss of other functions.
ANGEL INVESTORS	These are individuals or groups of individuals that tend to invest relatively small amounts of money in very early stage companies. They are willing to take greater risks with their money than VC investors in return for a piece of the company. Angel Investors tend to invest amounts of about \$250,000 to \$2 million.
ANIMAL EXPERIMENTS	In the initial process for developing a drug, experiments are usually performed on animals. Usually this is prior to any human clinical work. Unfortunately, animals can die in this process, but that death allows the drug to be made safer for human use.
APPLY FOR PATENT	An inventor may apply to the U.S. Patent and Trademark Office (PTO) for grant of a patent on an invention. The process starts by filing a document (called an application) with the PTO and paying the fees required by the government. The inventor will most often use the services of an intellectual property attorney for this purpose to ensure that all the rather complex rules of the PTO are followed.

ARTHRITIS	A condition in which there is an uncomfortable swelling of joints.
BUY AN INVENTION	This is the purchase of the rights to an invention. It is usually a relatively large amount paid at a time when the drug will still need to have significant amounts of money spent on it before any sales can be made.
CANCER	A disease in which certain cells in the body grow inappropriately and can cause death.
CARDIAC DISEASE	A disease of the heart.
CLINIC ENROLLMENT	This is the process by which companies find volunteers for testing of their drug. In some cases, these subjects will be healthy volunteers; in others, they will be individuals having the disease or condition that the drug will hopefully treat.
CLINIC HOLD	Sometimes a patient or group of patients may have an adverse reaction to a drug even after its approval for sale. In more severe cases, the FDA may stop sale of the drug until it is satisfied that the reaction was unlikely to be repeated or that it is something that can be tolerated. In other cases, the approval of the drug may be withdrawn, and the drug can no longer be sold.
CLINICAL TRIAL	This is the process required in the USA (and other countries) to ensure that the drug and its use are safe and useful. No drug can be sold until such a process is completed. This process attempts to protect the public from harmful or dangerous drugs. The process is very expensive, and in reality can cost many hundreds of millions of dollars. In this game, the cost is not as great, and every drug will eventually be allowed for sale, which is not the case in real life.
COMPETITOR	Any company that wants to start sales of generic drugs in competition with the company that obtained drug approval. Such a competitor may have to face a patent infringement lawsuit if the drug is patented.

COUNSEL	Another word for attorney or lawyer. A person licensed by the various states to assist others in legal matters. In this game, it generally refers to intellectual property attorneys or patent attorneys, who tend to have graduate degrees in the relevant field (such as biotechnology, molecular biology or chemistry).
DATA AMBIGUOUS	In clinical trials, no one can predict what will happen. Statisticians are used to try to determine how many patients must be treated to determine whether the drug is effective. In some cases, there may not be a sufficient number of patients and no definitive conclusion can be made. In those cases, a drug company can enroll more patients and see if the larger number will allow a conclusion to be made. Alternatively, the drug may be used in a different way to see if it is more efficacious. Either way, this is an expensive process, which may not result in data that will end in drug approval by the government.
DIABETES	A variety of different disorders or conditions in which insulin is not produced, or the level of insulin in the patient is not properly regulated, resulting in excessive glucose levels.
DRUG LIFE EXTENSION	This is really a fiction made for the game, but can refer to a situation where a drug is given new "life," in that it is found to be effective in treatment of new diseases or conditions, increasing sales.
DRUG SALES	The sale of the drug to patients as deemed appropriate by the FDA.
DRUG VALUE	The value of a drug generally increases with time depending on the use of that drug. However, the drug may be made less valuable if a new drug or procedure replaces it or the cost of manufacturing and marketing the drug is too great.
EARLY APPROVAL	When a clinical trial is so clearly successful, the FDA may indicate that the clinical trial can be terminated (ended) early. This is a great thing to happen to a drug company, but quite rare.

EFFICACY	This is a fancy term for the effectiveness of the drug. An efficacious drug is one that works well to treat the disease or condition for which it was developed.
FAVORABLE ACTION	A document from the PTO that indicates that a patent will be granted to the inventor. A few small requirements may need to be met, but otherwise this is almost the same as a notice of allowance.
FDA	The federal Food and Drug Administration, which reviews the clinical trial process and decides whether a drug will be allowed to be sold in the United States.
FINAL REJECTION	When the inventor or an attorney representing an inventor does not convince the PTO that an invention is patentable, the PTO may issue yet another rejection. If this is largely a repeat of the first such rejection it is called "final." That does not mean that the invention is not patentable. It simply means that the inventor or attorney needs to explain the invention more clearly to the PTO, or make changes in the application that will be acceptable to the PTO. This is not at all an uncommon occurrence for most inventions in the drug field.
FIRST REJECTION	The most common occurrence when a patent application is submitted to the PTO is for the application to be rejected. This is an indication from the PTO that there may be errors in the application, or that the inventor has not correctly claimed or described the invention. These are but two of many reasons for such a rejection. It is at this point that the inventor can go back to the PTO and indicate where they have made an error, or where the inventor has changed the final portion of the application (called the claims) to more clearly describe the invention. Given the complexity of this process an attorney is usually used to discuss the matter with the PTO. Indeed, it is possible for the inventor or attorney to actually speak to the person responsible at the PTO, called an examiner, to see how to make the application acceptable.

GENERIC DRUG	This is a drug that is sold without any patent protection. That means that in general (there are exceptions), any other company can sell the same drug and share in the market without any hindrance. The cost will generally be less than a patented drug. Usually, such generic drugs are sold after the patent on that drug has expired (patents last 20 years from the date of filing a patent application, but can be longer in some circumstances). After patent expiration, there is usually no legal impediment to prevent others from selling the same drug.
IND	This refers to an Investigational New Drug. It refers to a chemical that has not been approved by the government for sale for human treatment. It is the first stage in a long and very expensive process to get permission to sell a drug for human treatment.
INFECTIOUS DISEASE	A disease where a bacterium, virus or other agent enters the patient and causes differing effects.
INFRINGEMENT SUIT	This is a lawsuit in a federal district court where a patent owner sues a competitor for patent infringement. Patent owners claim that the competitor is selling a drug that is covered by the patent. The competitor may argue that the drug does not infringe (is not covered).
INTERFERENCE	This is an extremely complex process in the U.S. No other country has such a process. It is a mechanism to determine which of two or more inventors was the first to make the invention. Only one inventor can have a patent on that invention. Payments are made to compensate the attorneys who must represent each inventor in the process.
INVENTION	This is different from an idea. In this game, inventions relate to chemicals that can be used for treatment of one of the stated diseases, such as diabetes. Invention is an intellectual process (i.e., you perform it in your mind) of creating a new drug or a new use for an existing

drug. This invention can then be sold to a drug company (usually a biotech company or a pharmaceutical company) or licensed.

LICENSE

This is like renting an invention. You pay a small amount of money up front and then make other payments (sometimes called milestone payments) as the drug progresses through various stages. Other payments also include royalties that are generally paid on an annual basis dependent upon how well the drug sells. This is only approximated in the game.

MORE INFORMATION

When the PTO asks for more information, it simply means the examiner would like to have help in understanding the invention, or data that demonstrates why the invention is patentable over what others have done before (prior art). In other cases, it may be a request to show that the drug actually works as the applicant (inventor) claims. This commonly happens in drug-type inventions, since data may not be provided in the application when it is filed, but is only available later.

MORE TESTING

The FDA may not be satisfied with the data that a company provides. It may indicate that a drug is not going to be approved unless other tests are performed. This of course increases the cost of obtaining drug approval significantly.

NDA APPROVED

This is the indication from the FDA that the drug is ready for sale to a human population. It is New Drug Application approval.

NEW ART

New art is a term used in the patent world to refer to any activity that could reflect the work of people before the inventor made the invention. It is a very complex area of law and includes not only publications in journals, but also other patents and work done in foreign countries. Art can even include work of others that could not have been known to the inventor when the patent application was filed. In the PTO, this art may be discovered at any time. Indeed, the PTO may not

find it, but the inventor might. If the inventor finds such art, it must be shown to the PTO if it is more relevant than art that the PTO possesses.

NEW LAWS

The U.S. government will periodically pass new laws that relate to the process of obtaining a patent. In addition, the court of appeals for the federal circuit may publish opinions that will affect the process (called prosecution of the patent) in a way that requires special attention. Such new laws need to be considered carefully to determine whether the strategy of prosecuting one patent application is correct.

NOBEL PRIZE

This is a preeminent prize awarded to those who have excelled in their field. It is awarded in Sweden yearly in different fields, including medicine.

NOTICE OF ALLOWANCE

This is an indication from the PTO that it agrees with the inventor that an invention is patentable and a patent will be issued. It is rare to get such a notice early in the patenting process, but it does occasionally happen.

ORPHAN DRUG STATUS

Certain drugs are given a special status when they are tested to treat a disease or condition from which very few people suffer. The U.S. government wants to encourage companies to develop drugs for such small populations despite the poor profits made by selling these drugs. If such status is obtained, a period of seven years of exclusivity can be granted (this is different from a patent) for the sale of that drug. This is not reflected in the game in this way.

PATENT

This is a formal government document from the PTO that allows the owner of a patent to prevent others from using their invention. A patent does not permit the inventor to actually use and sell their invention. Others may have patents covering the same drug. A patent is good only in the country from which it is issued. Most drug companies will apply for patents all over the world.

PATENT EXPIRES

A patent has a life of 20 years from the filing date of the patent application. During that time period, the owner must pay certain fees to keep it "alive." If those fees are not paid, the patent can no longer be used by the patent owner to sue competitors.

PATENT GRANT

This is the final step in the patent process where a formal document is provided to the inventor. Fees are again due to the PTO for this privilege.

PATENT TERM EXTENSION

This is a complex area that deals with a situation where the approval of the drug takes a long time. This means that the value of 20-year term of the patent has significantly diminished. In light of this, the U.S. government will extend the term of the patent by some amount to compensate the patent owner for the loss of time.

PATIENT ENROLLMENT

The process by which companies get patients to volunteer to test their drug.

PATIENTS

These are individuals suffering from a disease or condition that drugs will hopefully treat.

PEDIATRIC TRIAL

A trial of the drug performed on children. Very few drugs are tested in children as they are developed for the larger adult population. The U.S. government encourages such trials by giving a period of exclusivity of six months in some cases.

PHASE 1

This is the first part of a clinical trial where the safety of the drug is first assessed. In this stage, healthy volunteers are administered the drug to determine that it is safe and produces no bad (or adverse) reactions that cannot be tolerated. Note that some adverse reactions will be of little consequence for some drugs but can prevent others from being used. For example, a drug for treatment of an otherwise fatal cancer may cause nausea (vomiting) and still be allowed for clinical treatment. Another drug for treatment of hair loss may not be approved if it also caused vomiting.

PHASE 2

This is generally the second part of a clinical trial. In this phase, patients suffering from the disease or condition may be treated with the drug. Some preliminary tests may be performed to see how much of the drug is needed to have the desired effect. This process may be repeated several times and in different ways before the next part of the drug approval process is attempted and is much more expensive than Phase 1.

PHASE 3

This is generally the final stage before approval of a drug. Many failures can occur here. Here, a population of individual patients are treated with the drug in a random manner so that a statistician can conclude the drug's effectiveness. It is extremely costly to perform this process and can take many years.

PROSECUTION

This is the process of obtaining a patent from the filing of the patent application through patent issuance.

RE-EXAMINATION

This is a process that allows anyone to challenge the issuance or granting of a patent in the U.S. In general, if a new piece of art that was not considered in the prosecution of the patent is discovered, it can be sent to the PTO with a request for re-examination. There is a fee paid to the PTO for this purpose. In rare cases, the PTO itself may start the process. Once started, the process is similar to the prosecution of a patent. After this process, the patent may be issued again in the original state, or with some changes.

Another process that can occur with issued patents is called re-issue. This is where the patentee asks that the PTO consider some new art or other issue that has come up and indicate whether the patent can be reissued as a new patent despite that art. This is not dealt with in this game.

REVENUE

This is money that is paid when a drug is sold to a patient or hospital.

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PRESCRIPTION FOR SUCCESS

REVIEW AMBIVALENT The FDA may find that the data is not convincing in terms of drug value or efficacy. The FDA then provides an indication to the company that it is not sure that it will approve the drug for sale. The company can then develop more data for the FDA to review or attempt to demonstrate the value of the drug in other ways.

ROYALTY This is a payment for the right to use a drug (in this game). It is paid to the owner of the patent or to the owner of the invention (even if not patented in some cases). It is a way to compensate the inventor for the mental process that the inventor allows others to use.

RULES OF PATENT OFFICE The PTO has a large book of rules that the examiners and others in the office must follow. Indeed, attorneys and others who attempt to get patents granted must also follow those rules. These rules are subject to a statute governing the grant of patents, in U.S. Code 35 (the patent statute) and even the constitution of the United States. In addition, judges in various district courts, the court of appeals for the federal circuit and the supreme court may interpret those rules and statutes. (Other countries have similar patent offices, rules and courts.)

SECOND CLINICAL TRIAL In some cases, companies will perform more than one clinical trial simultaneously, for different treatments. This is a very costly process to undertake but can significantly increase the chance of success in the clinical trial and in later sales.

VC – VENTURE CAPITALIST This is a term used to refer to groups of people or companies that invest in other entities (partnerships or companies usually). In the biotechnology field, VCs are usually willing to invest relatively large sums in the range of \$2 million-10 million. In return, they will be entitled to a portion of the company or some significant return on their money.

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