INSTITUTE FOR THEOLOGICAL ENCOUNTER WITH SCIENCE AND TECHNOLOGY

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The stars, in their stately procession through the night sky, stopped over the house where Jesus, Mary and Joseph were. So we read in St. Matthew's Gospel. Yet, for all their dignified appearance, we know that the stars are boiling masses of particles. They remain in God's hands and are obedient to his wishes. We may re-phrase the "Science Finds, Industry Applies, Man Conforms" of the Century of Progress Exposition in Chicago in 1933: "God Proposes, God Disposes, Creation Conforms." When God speaks, all creation listens.

As sedate as God may seem, he is hardly that proper in his relations with those he loves. God is never "standoffish" with the works of his hands. They were created because God loves them and, citing St. Thomas, God will never lose any of the beauty that he has created. God's love for his creation will never diminish; it will only grow stronger as it is reciprocated in our lives. God truly loves us and if we return that love, his love for us "will become deeper", if God's love can become deeper. How can we show that love of God in our lives? "Love one another as I have loved you." That is a commandment, not a velleity.

One way that we can love one another is to impart to children as best we can the loving relation God has for them and with them. We can teach them that God loves them in and through his creation. We can sing to the children of the gifts God has given them and us in the stars, the galaxies and all the celestial inhabitants. We can sing of the fury of their being and of their orderly procession through the heavens. We can look within and see the almost infinite delicacy of our bodies. We can relate these gifts of God to the imagination of the young. We can express a little of the love which God has bestowed on them in creation and in redemption.

What a joy to raise up a generation of children dedicated to the love of God through love of creation and of the neighbor! In its own way that would fulfill scripture: "you must love the Lord your God with all your heart, with all your soul, with all your strength and with all your mind, and your neighbor as yourself." Then the bitter conflict between faith and reason, faith and science, would be muted. Pray that that day come soon. May God bless you all.

Robert Brungs, S.J.

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ANNOUNCEMENTS

1. As reported in the last Bulletin, ITEST has received a generous grant of $50,000. from the Our Sunday Visitor Institute (OSV) to partially fund the first year of the educational project in faith/science, *Exploring the World, Discovering God (EWDG)*. The OSV has provided funding for a number of ITEST projects over the years, more recently, among them, our weekend conferences of 2001 and 2003 *Genetics and Nutrition* and *Globalization: Christian Challenges* respectively. The OSV fully funded our twenty-eight minute video produced in 1987, *Decision: Scientists in the Church* (now available on our web site) Again we are grateful to the Board of the OSV not only for their monetary support but for their encouragement of our work in the faith/science arena.

2. We announce with sadness the death of Mrs. Margaret Ohrman on November 21, who with her husband, Paul who died a few years ago, were generous benefactors and involved members of ITEST over the years. Often called The "Godmother of Catholic education," Mrs. Ohrman was vitally interested in improving and enriching school curricula, by donating to many projects which furthered the cause of instruction and education in the local area schools in both St Charles and St Louis, Missouri and beyond. We commend her to your prayers. May she rest in the peace of Christ.

3. **ALERT!** ITEST phone numbers have finally been changed from (314)-977-2703 to **(314)-633-4626**. Please note that change in your records. Check the front page of the Bulletin for updated figures.

4. The date for our October 20-22, 2006 workshop entitled, *An Education for the Faith/Science Ministry*, has been set. This workshop will lay the groundwork in theology and science for the educational modules in faith/-science, the program we plan to pilot in selected parochial schools from kindergarten through fourth grade. A number of publishers have provided us with their textbooks on religion and science for examination, analysis and study. We will be holding interviews with prospective applicants for Project Manager/Coordinator in January with a projected start on February first.

4. We ask your patience as our new web site is still under construction although you may access it at **www.faithscience.org.** Dr. Greg Pouch is working on it now and when it is completed the site will be much easier to navigate than in the past. In the meantime Greg has provided a link to the old web site which is still accessible. Or you can simply access the old web site if you wish at **http://ITEST.slu.edu**

TEILHARD DE CHARDIN AND THE DIALOGUE BETWEEN SCIENCE AND RELIGION

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Abstract

We can find in Teilhard's writings many points of interest for the dialogue between science and religion. I have selected three of them in his understanding of science, matter and human evolution. The first is his high esteem for science and its role in human history. Science for him represents the line along which evolution progresses at our human level and it prepares people to find the profound and hidden meaning of reality. This understanding of science may serve as a good starting point in the science-religion dialogue, since it recognizes a potentiality in science to be interpreted in religious terms. The second is his understanding of matter which surpasses all matter-spirit dualism. Matter for him has an internal dynamism, which led it to the spirit, through the process of cosmic evolution. The third is his conception of human evolution as a part of cosmic evolution. By this, the consciousness of man (noosphere), progresses along the line of increasing unity to finally converge into an Omega Point, where it finds its ultimate fulfillment.

Keywords: Science-religion dialogue, Teihard de Chardin, science, progress, matter-spirit, complexity, evolution, convergence, consciousness, socialization, globalization.

Introduction

Pierre Teilhard de Chardin (*1881-1955*), Jesuit priest and paleontologist, developed throughout his scientific career an original system of thought which may be placed at the boundaries between science, philosophy, theology and mysticism. During his life the publication of his non-scientific writings was barred by ecclesiastic authorities, but circulated in private copies among his friends. When Teilhard's writings began to be published, after his death in *1955*, they produced an enormous impact and were rapidly translated into many languages. The publication of all his writings has been a slow process (Teilhard de Chardin, *1955-1976*). In the original French, the first volume of Teilhard's works *(I, Le phénomène humain)* was published in *1955*, and the last *(XIII, Le coeur de la matiere)* in *1976*. Other writings and letters were also published during this period. In this article references to his writings will be given to the French edition, by title of the essay in the original French and its translation, volume of the complete works and page numbers.

The early interest for Teilhard's ideas can be measured by the publication, between *1956* and *1980*, of about *3000* books and articles about them in different countries. A very extensive bibliography about Teilhard can be found in Polgar *(1990, III, 359-563)*. Teilhard's thought has been the object of many studies which analyze its scientific, philosophical and theological aspects, among them Crespy *(1961)*, de Lubac *(1962)* Rideau *(1965)* and Chauchard *(1965)*. After *1980* the interest for Teilhard seems to have declined, but we can see something of a revival recently. In the new dialogue between science and religion, which began about *1970*, Teilhard is not often mentioned. This may be explained by the preponderance of authors in this field from the Anglo-Saxon tradition, where Teilhard's ideas are less popular. However, we can find in his writings many points of interest for this dialogue. I have grouped some of them around his ideas about: i) science, ii) matter and iii) human evolution. Because Teilhard assigns a particular meaning to some terms, some are given here in the original French also.

The religious aspects of science

The first point which may help in the dialogue between science and religion is Teilhard's high esteem for science and its role in human history. For him science is more than a body of knowledge; it is in his words, *Le gran afaire du Monde* (the great endeavor of the world), "a vital human function, as vital as nutrition and reproduction." He goes even further and proposes that we must believe in scientific research as the source, when followed with faith, of a unique human-Christian mysticism which may contribute to a true human unanimity. *(Sur le valeur religieuse de la recherche* - On the religious value of research, IX, 258-263). In a short essay, written shortly before his death, he left his last opinion about what sciences meant to him *(Recherche, travail et adoration* - Research, work and worship, IX, 281-289). In this essay, Teilhard insisted on the fact that scientific research has become quantitatively and qualitatively the main form of human activity. Writing about the problems of young Jesuit students dedicated to science, he referred explicitly to the conflict between religion and science. He stated that a solution of this problem requires a rethinking of the Christian message in the light of science, especially incorporating the ideas of cosmic evolution. He concluded by suggesting that the researchers of today can be considered as the *avant-garde* of a society progressing toward a new form of worship. Thus we can say that Teilhard very optimistically saw science as the motor of human progress. Moreover, science was not only a source of understanding about the universe, but opening toward a more profound understanding of reality, it had in itself a religious character.

In order to understand Teilhard'sposition about science we have to consider his view about human evolution as part of total cosmic evolution. We will explain this shortly in next section: here we can anticipate that for him the universe was in a state of cosmic evolution, human evolution being an integral part of this cosmic evolution. A central part of human evolution was precisely that formed by scientific work. Thus, science for him represents the line along which evolution was progressing at human level. Since the main characteristic of Teilhard's view of evolution was its convergence toward its fulfillment in the Omega Point, which he identified with God, as we will later see in greater detail, motion in this direction acquired a religious meaning. In such a convergent universe, science and scientific research has to be seen as cooperating to its consecration and consummation in God. In this sense, Teilhard was saying that science, by its relation to the axis of convergence of the universe, was acquiring a mystical character. In a universe in which everything is directed finally to a convergence through the spirit, we should recognize in science itself a profound meaning of sanctity and communion. In a true sense scientific work, which consists in developing, through knowledge, our consciousness of the world, becomes what may be called a priestly operation. It consists in a contribution to the progress of a world which is finally oriented to God *(La mystique de la science* - The mystique of science, VI, 202). Teilhard, introducing from Christian faith the role of Christ in the converging universe, took a further step in the line of understanding the meaning of science. He identified Jesus Christ as the Omega Point, already present in the world. He discovered that, through Christ's incarnation, the very Pole of the convergence of the universe, which is Christ himself, has been made present in the very heart of matter, in order to attract and consummate the whole movement of evolution. For him, then, Christ is not a stranger in the world, but the very same Center of its convergence. Toward him and for him, Life and Light of the world, through human work and effort, the universal convergence of the spirit is fulfilled *(Science et Christ ou analyse et synthese* - Science and Christ or analysis and synthesis, IX, 61). Teilhard's insistence in the demands of the converging universe for the presence of Christ may create some misunderstandings. By this he wanted to express the unity of the total liberty of the Incarnation with is quasi-necessity, since the world cannot achieve the convergence and unity toward which it tends without the mediation of the Man-God. Thus Christ becomes central to the whole movement of evolution.

Teilhard's understanding of both the role of science and the role assigned by Christian faith to Christ and interpreted by him in the process of evolution is fundamental in his position about the religious character of science itself. In this sense, science is not only not opposed to religion, but in some way, a preparation for it. It prepares man to find the hidden profound meaning of reality. For Teilhard this profound meaning is based on the convergence of the evolution toward God. Once we accept that our universe is a converging one toward union with God, through the path of increasing consciousness, scientific work acquires for itself a religious sense. In a conference on the relations between science and religion, he distinguished the way of science as that of analyses and that of religion as syntheses. Taking into account his image of the universe, we can understand that for him: "Science with its analyses doesn't have to trouble us in our faith. It must, on the contrary help us to understand better, comprehend and appreciate God" (*Science et Christ ou analyse et synthese* - Science and Christ or analysis and synthesis, IX, 61). Talking about the conflicts between science and religion, he concluded that "after two centuries of passionate struggle neither science nor faith has succeeded in discrediting its adversary. On the contrary it is becoming obvious that neither can develop normally without the other.... Neither in its impetus nor in its achievements, can science go to its limits without becoming tinged with mysticism and charged with faith .... Religion and science are the two conjugated faces or phases of the same complete act of knowing" (*Le phénomène humain* - The phenomenon of man, I, 316-317). "A science charged with faith" is precisely the title of the chapter dedicated to Teilhard by Henderson (1986). In this chapter Henderson develops Teilhard's proposal of bringing together science and theology in a passionate search for God who must be recognized to be present in both. Introducing the Christian mystery of the incarnation of God through Christ in the universe, Teilhard went even further and states: "In consequence it is vain and unjust to oppose science and Christ, or to separate them as two domains estranged one from the other. Science by itself cannot discover Christ, but Christ fulfills the desires which arise in our heart in the school of science" (*Science et Christ ou analyse et synthese*, IX, 62).

Accustomed as we are to the usual solution of keeping science and religion separated with no interaction between them, we may think Teilhard's proposal unrealistic if not absurd. Is not science in itself atheistic? How can it become in any way a path toward God? But even accepting the separation of science and religion we cannot let them ignore each other; a fruitful dialogue between the two is necessary. Even proponents of the complete independence between the two, as Stephen Gould (*1999, 221-222*), himself a strong critic of Teilhard, agrees to a certain amount of dialogue. Theology cannot progress isolated from the continuous growth of the knowledge about the natural world that science keeps producing. Medieval theologians were already aware of the need in theology of a correct knowledge of the world. On the other hand science cannot cut itself off from the inspiration which comes from religion. Though a necessary autonomy is needed in each field, mutual interaction will benefit both science and religion. Maybe Teilhard goes a little too far in his proposal of a continuity between the two, but his ideas show us a possible path through which we should dare to walk.

A new concept of matter

What has been called "scientific materialism" has been acknowledged as a source of confrontation between science and religion (Barbour, 1990, 7-9). Scientific materialism is based on two assertions: matter (including energy) is the fundamental reality of the universe and science, the study of matter, is the only valid knowledge. The first is a metaphysical assertion and the second an epistemological assertion based on the first. Thus, the only reality is the material which is known through science. Materialism implies a reductionism, that is, all knowledge can be reduced to that of the most simple constituents of matter. In consequence, no other reality exists outside that of matter. This position rejects the consideration of any other reality as baseless spiritualism and animism. These ideas are very extended since as Barbour says: "Because scientific materialism starts from scientific ideas, it carries considerable influence in an age that respects science." In the dialogue with this mentality Teilhard's understanding of matter may be very helpful. He began by rejecting all matter-spirit dualism, and presented a concept of matter which included a spiritual dimension. He tried to understand the nature of matter, not from the point of view of its simplest particles (quarks and leptons) but from the evidence of consciousness in man. If man is a conscious material being, this quality of reflex consciousness, explicitly and clearly present in the human person, has for Teilhard to be present in all matter. This led him to propose that there is an inside (*dedans*) of matter, besides its outside (*dehors*), which is the object of science (*Le phénomène humain*, I, 49-64). To this twofold character of matter corresponded two types of energy: a tangential (*tangentielle*) energy, which correspond to the physical energy, and a radial (*radiale*) energy, which is responsible for the converging evolution of matter in the line of greater complexity and greater consciousness. The radial energy is also called the spiritual energy, since Teilhard identified spirituality and consciousness. These concepts of matter and energy were a consequence of his vision of the continuity of the evolution of the universe from elementary particles up to man.

Matter for Teilhard has, then, an internal dynamism which included the spiritual and led it in an ever-increasing spiritual dimension. We observe that evolution proceeds along the line to greater complexity. To this increase in complexity corresponded an increase in consciousness, which Teilhard identified with a greater spirituality. As beings evolve from inert matter to life and consciousness, their spiritual dimension keeps increasing together with their complexity. For him consciousness, fully present in man, must also, in a primitive manner, exists in all material beings. Teilhard distinguished seven grades or levels of matter according to its place in its convergence movement to the spirit. Thus he wrote about formal and concrete matter at the lowest level, and about universal, total and relative matter at a higher level and finally about liberated and resurrected matter. Teilhard recognized the two basic processes, toward matter and toward the spirit, (materialization and spiritualization) to be strongly linked together like the two faces of the same thing (*Le noms de la matiere* - The names of matter, XII, 449-464). Behind this understanding was what he called the "spiritual power of matter" (*La puissance spirituelle de la matiere* - The spiritual power of matter) XII, 467-478), which allowed matter to become the matrix of the spirit. Thus for Teilhard matter itself had a dynamism which makes it evolve toward the spirit in man. In its final development, through the human spirit, matter itself finds its final accomplishment in the union with God. For Greek philosophers matter was considered as a hindrance to the spirit to be overcome. This was the source of the matter-spirit dualism present at all times in much of western thought. Teilhard giving to matter the power to progress to the spirit, overcame this dualism. He ended his considerations about matter with a mystical "Hymn to matter" in which matter is saluted as the "powerful Matter, irresistible Evolution, Reality always being born ... divine milieu full of creative power, ocean agitated by the Spirit, clay kneaded and animated by the incarnated Word" (*Le coeur de la matiere* - The heart of matter, XIII, 75-91). Thus, the proposal of scientific materialism of matter as the only reality, the seed of atheism, can be overcome by showing the inner dynamism toward the spirit of this same matter in the overall scheme of the converging evolution whose final end is God himself.

From Teilhard's point of view, the nature of matter, as known by science, is in itself incomplete, since it cannot explain the evolution of matter toward greater complexity and consciousness, which finds its full expression in man. However, Teilhard did not introduce a dualistic principle to explain consciousness; on the contrary he put in matter itself the power to evolve into consciousness. For Teilhard consciousness was in fact a dimension of matter, which is linked to its complexity. As matter becomes more and more complex greater degrees of consciousness appear. Consciousness constitutes what we may call the spiritual dimension. Matter and spirit were, then, not two opposing reality, but two dimensions of the same reality. This understanding of matter-spirit reality cannot be understood without Teilhard's idea of a convergent universe toward greater consciousness or spiritual dimension, attracted by the super-conscious and super-spiritual Omega Point. All the potentialities of matter depend finally on the complete dynamic structure of reality which can only achieve its final completion in the union with the Omega Point.

The human convergence

The third aspect in Teilhard's thought which may help in the dialogue between science and religion is his conception of human evolution. He considered cosmic evolution as an intrinsic dynamic nature of the universe which unfolds from the simple material particles, through the living beings (biosphere), to the conscious dimension of man (noosphere), along the line of increasing complexity and interiority or spirituality. For him evolution did not stop at the human consciousness, but it must proceed further through human evolution finally to converge into an Omega Point, where it will find its ultimate fulfillment. This Omega Point must be personal and Teilhard identified it with God. This convergence, an essential point in Teilhard's thought, is realized at the level of the noosphere, that is, through the human evolution, by a unifying movement, attracted by the personal, transcendent and divine Omega Point (*Le phenomene humain*, I, 286-303).

This last stage of cosmic evolution will take place through what Teilhard calls the "human collectivation" (*la collectivation humaine*) or "socialization." What he means by this was the subject of many of his essays, some of them collected in volume V, under the title *L'avenir de l'homme* (The future of man). In these essays he recognized that his idea of the noosphere and its spiritual evolution had been hard to accept. For him, at the human level, evolution is linked with his understanding of progress. He understood progress as marking the way of human evolution, which finally tends towards a convergent unity or toward a divergent plurality. A stage in this process should be the creation of a unified science and a common goal accepted by all. In order to avoid falling into a divergent plurality, however, these two elements present in progress are not sufficient for a convergent motion. A common attraction is needed by a "some one", a personalized Center of attraction which through the force of love will accomplish the final unification of all consciences (*Réflexion sur le progrès* - Reflection on progress, V, 85-106). This is a diffcult point. Teilhard was aware that man is free and progress at human level is not an automatic movement. There are many roads along which man can make his way. Teilhard reduced them to two: "evolution of plurality" and "evolution of unity." The first leads to divergence, where the elements tend to oppose each other, moved by what he called a "mystique of separation." This tendency can be seen in the growth of particularisms and nationalisms, which seek satisfaction in a progress of a group against the others. This for Teilhard was to introduce, in the evolution at the conscious level, an element of desegregation and death. The only alternative was, then, through a universal socialization, to arrive at a true unification. He called this the "great option" (*La grande option* - The great option, V, 57-80).

The modern phenomenon of globalization, imperfect as it still is, can be seen as corresponding to this convergent movement of the noosphere. Teilhard saw this process as a phenomenon irresistible both on a planetary and cosmic level. He describes this process as a first phase, which may be considered as forced, which must be followed by a free one. (*Un grand événement qui se dessine: la planetisation Humain* - A great event which is appearing: the human planetization, V, 159 -175). The force behind this process, which must be realized in freedom, cannot be other than love. This may seem strange, but Teihard used this word in the very general sense of mutual internal affinity (affinité mutuelle interne). Thus love is at the human level a continuation of what he called the "radial" energy, that is, the energy that has been the driving force of evolution ever since the first synthesis of inanimate matter. At the human level, that is for persons, this force takes the form of love, for love is the only force that can achieve unity without negating individuality (*L'énergie humain* - The human energy) VI, 180-192). In his own words: "Only a union realized for love and in love has physically the property not only to differentiate, but to personalize the elements that it organizes." His conception of the human evolution is, then, a dynamic one, tending toward unity through the impetus of love, without losing the personality of those who are united. The influence of the natural sciences does not allow for other approach, since they show a dynamic universe in a converging evolution. Social sciences show us also a progressing motion of humanity, which tends to some kind of unity.

In this context, Teilhard introduced the role of the Christian faith as a force which works in the same direction as the human convergence. For him Christianity has to become the religion of the future (*la religion del'avenir*) by discovering what he calls the "Human Sense" (*Sens Humain*), which is really implicit in it, as he recognized. The human sense is the drive of all men toward a unified achievement, and for a Christian this achievement is fulfilled by the union of all in Christ. Thus, he added that "the light of Christ is not eclipsed by the shining of the ideas of future, research and progress, but it occupies the center which sustains its fire." He concluded that Christ is the only one who can save the human aspirations of our time (*Le sense humain* - The human sense, XI, 21-44).

In the epilogue of his fundamental work (*Le phénomène humain*, I) entitled "The Christian phenomenon (*Le phénomène chrétien*), Teilhard ventures a Christian interpretation of the whole cosmic evolution in which the Omega Point was identified with the figure of Christ. The universe, then, through the convergence of humanity tends really to an ultimate unity which can only be achieved in the union with Christ. Christ is, then, the Presence of the Omega point in the human history, attracting human progress toward himself, and thus helping it to its achievement. In this interpretation, the cosmogenesis of evolution becomes truly a Christogenesis, as he identifies the pole of the evolution with the incarnated Christ. The unity of men and through them of all the universe with Christ is what he calls the "total" or "universal" Christ. These ideas are more fully expanded in his last essay, "*Le Christique*" (XIII, 93-117), written in March 1955, just days before his death.

We have mentioned that the modern phenomenon of globalization may be interpreted as a sign, weak as it may be, of the human convergence postulated by Teilhard. This sign can be seen also in various other phenomena, such as the increase in world communications, rapid global transportation, concern for international affairs and strengthening of the role of the United Nations. However, modern times are witness also to many divergent motions of violence, wars and the modern phenomenon of terrorism. In view of this, one may ask if there is a reasonable ground for Teilhard's optimistic view. It is a matter of weighting the evidences at hand, though we are still too far away to see clear signs of a true human convergence. We must not forget that Teilhard developed his vision during the time of two world wars and the tragic divisions present during the cold war. Today we need some of his optimism to be able to see, through the many dark signs, the light at the end of the tunnel which shines as a hope for the future of mankind.

Conclusions

Accustomed to the usual solution of keeping science and religion separated with no interaction between them, we may think Teilhard's proposals unrealistic. But science and religion cannot ignore each other without very detrimental effects for both, and a fruitful dialogue between the two is necessary. Religion, or better theology, cannot progress isolated from the continuous growth of the knowledge about the natural world, which science keeps producing, and science cannot cut itself out from the inspiration, which comes from religion. In the present dialogue of science and religion, the thought of Teilhard de Chardin may offer some helpful insights. We have looked into three aspects: the importance he gives to science as the main human endeavor which has in itself a religious character; his open concept of matter which includes the spiritual dimension and the convergence of the evolutionary process through the unity of mankind. Though he addressed his vision to all men of good will and took its foundation from what science tells us of our evolving universe, he made a synthesis with religious thought. God is present for him in the horizon of both science and religion, indicating that a convergence of the two must exist. Teilhard insisted on the need of accepting the evolutionary image of the universe presented by modern science in religious thinking. This will imply serious changes in some religious understanding, but these are necessary in order to keep open the dialogue between science and religion. As we have seen, two of these, proposed by Teilhard, are the acceptance of a new concept of matter, which includes a spiritual dimension and the convergent evolution at the human level through a process of unification. The latter opens also a fruitful dialogue with Christian faith about the role of Christ in an evolutionary universe.

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PATENTING OF BIOLOGICAL MATERIALS

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The U.S. patent statutes defines "patentable inventions" as follows:

§ 101 Inventions patentable

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 therefore, subject to the conditions and requirements of this title. (July 19, 1952, ch 950, § 1.66 Stat. 797.)

In the 1980 case of *Diamond v Chakrabarty,* the U. S. Supreme Court ruled that living cells fall within the scope of "compositions of matter" that can be patented. In the 25 years since the *Chakrabarty* decision, the biotechnology industry has grown tremendously in terms of the money invested, people employed, and products produced. This growth in the biotechnology industry has been accompanied by a surge in the number of patent applications filed for biotechnology inventions. Patent protection has now been granted on thousands of microbes, and has now been extended to multicellular animals, including mammals. Although the horses appear to be well out of the barn when it comes to patenting living cells, genes, and even animals, there are still those who question whether the patenting of such entities is a good idea and who fear that the trend towards the awarding of such patents promotes reckless (or immoral research) and/or may be immoral in and of itself.

This paper explores the role of the United States patent system in providing intellectual property protection for biotechnology inventions. First I discuss the purposes of the patent system and explain how the system is administered to achieve these purposes. This is followed by a specific discussion of how the patent system has been applied to biotechnology inventions. This discussion includes a review of important developments over the last century as well as an analysis of how the system is now being applied to emerging technologies. Particular attention is given to concerns that have been expressed over the years and whether these concerns have turned out to be well-founded. Finally, insight, based on this historical perspective, is provided into the challenges and opportunities that lie ahead in our efforts to promote biotechnology innovation without compromising our fundamental values.

I. Intellectual Property

A. Definition of "Intellectual Property"

"Intellectual Property" can be defined as:

> Creative ideas and expressions of the human mind that have commercial value and receive the legal protection of a property right.... Intellectual property rights enable owners to select who may access and use their property and to protect it from unauthorized use. (United States Department of State website.)

There are several legal mechanisms for protecting rights to inventions, writings, slogans and other types of intellectual property. These mechanisms include copyrights, trademarks, patents and trade secrets. These forms of protection differ from each other in several important respects, including the methods of obtaining them, their duration, and the subject matter to which they pertain.

Patents and trade secrets are the most important intellectual property rights available to most biotechnology researchers. These two forms of protection are briefly introduced and contrasted below. This is followed by a more detailed introduction to the patent system.

B. Patents

A patent represents a set of legal rights that are bestowed on an inventor by the government when an invention satisfies certain specific requirements. Each country has its own patent laws. In the United States, the recipient of a patent has the right to exclude others from making, using, or selling the invention in the U. S. for a period of 20 years measured from the original filing date of the patent application. The patent laws of other developed countries grant similar rights.

The essence of the Unites States patent system is an exchange between the inventor and society: in return for fully disclosing his or her newly developed intellectual property to the public, the inventor receives, for a limited period of time, the right to *exclude* others from practicing the invention. The patent system does not provide an affirmative right to practice the invention — only the right to prevent others from doing so.

This exchange between inventor and society achieves two primary purposes. First because the inventor is rewarded with a preferred status for developing an invention, innovation is encouraged. Furthermore, and equally important, a complete disclosure of the invention is provided to the public thereby discouraging secret activities and expediting the pace of innovation.

The patent system has been fine-tuned over the years to achieve its goals by carefully confining the extent and duration of patent coverage, and to emphasize full and complete disclosure, for all to see, of how to make and use the invention.

C. Comparison of Patents to Trade Secrets

The primary alternative to patents is trade secret protection. Trade secrets are quite different from patent protection both in the manner by which they are obtained and in the protection they provide. A trade secret can be anything that is known only by a particular person or business entity and that gives the person or business entity an advantage over competitors.

Unlike the process for obtaining a patent, it is not necessary to apply for trade secret protection. Therefore, in terms of the procedural requirements for obtaining protection, trade secret protection is much easier to obtain than patent protection. The primary requirements for trade secret protection are that the idea, invention, or information must actually be secret and the holder of the secret must take appropriate steps to maintain secrecy. Inventors must often choose between patent protection and trade secret protection; however, once an invention is known to the public it, by definition, can no longer be kept as a trade secret.

In sharp contrast to trade secret protection, a critical aspect of the patent system involves *full public disclosure* of how to make and use the invention. This full disclosure occurs when a U.S. patent is granted and/or a patent application is published (typically 18 months after filing). Therefore, an inventor can initially pursue patent protection while maintaining trade secret protection; however, ultimately, these two forms of protection are mutually exclusive.

II. The Patent System

A. Brief History of the Patent System

In 1623, the British Parliament passed the Statute of Monopolies thereby abolishing all past monopolies and denying the Crown power to grant future monopolies. Parliament recognized that patents, unlike other monopolies, were not detrimental to society and, therefore, patents were exempted from the terms of the Statute of Monopolies. The Statute of Monopolies allowed for the granting of limited monopolies made to inventors of new "manufactures." The statute confined monopolies to the first and true inventors of manufactures not known or used before. The granting of monopolies to inventors was designed to reward and encourage those who invested time, money, and effort to create a product that would benefit society at large.

The Statute of Monopolies was an important and influential piece of legislation and it can be assumed that the American colonists were well aware of its terms. Although several of the colonies offered patents during the 1700's there was not a great deal of interest in them. By 1787 when the Constitutional Convention was held, interest in science and technology had increased and the framers of the constitution were aware of several ways in which scientific research could be encouraged and rewarded. Although there was some support at the Convention for other forms of encouragement, the patent system was adopted after very little debate. The founding fathers of our country included within the constitution of the United States a provision calling for patents and copyrights to "promote the progress of science and the useful arts." Thomas Jefferson's writings confirm that he, as one of the founding fathers of this country, believed in the importance of fostering human ingenuity: "Ingenuity should receive a liberal encouragement." V Writings of Thomas Jefferson, at 75-76.

It did not take Congress long to legislate in accordance with its Constitutional powers. In 1790, just three years after the adoption of the Constitution, the first patent act was passed. The Patent Act of 1790 provided that, upon issuance of the patent, the patentee must submit a description of the invention that would "distinguish [it] from other things before known or used." With this requirement, Congress ensured that in return for the grant of a limited monopoly, the public would receive the knowledge of how to use an invention that was distinguishable from anything already in the public domain.

B. Requirements for Patentability are the same for all Technologies

The constitutional and statutory basis for the patent system is not specific for any type of technology. Rather, the same requirements apply to all technologies and the courts have repeatedly emphasized that patent protection should be available to a broad range of technologies. This approach is consistent with the goals of broadly promoting useful human endeavors and the efficient public dissemination of new innovation and ideas. As stated by the U.S. Supreme Court: "Congress intended [patentable] subject matter to include anything under the sun that is made by man" S. Rep. No. 1979, 82d Cong. 2d Sess. 5 (1952); H.R. Rep. No. 1923, 82d Cong. 2d Sess. 6 (1952). *Diamond v. Chakrabarty*, Supreme Court of the United States.

C. Attributes of Patent Protection in the United States

When a patent is issued by the U.S. Patent Office, it grants to the inventor, or the inventor's assignee, for a period of 20 years measured from the original filing date of the patent application in the Patent Office, the right to exclude others from making, using, or selling the invention within the United States. As a result of the thorough examination given to each application, every patent carries with it a presumption of validity. Despite the presumption of validity accorded to each patent, a patent may be held to be invalid after it has been issued. Any claim of a patent that is found to be invalid cannot be enforced against infringers.

D. Patents Provide No Right to Practice an Invention

The rights conferred upon a patentee are very confined in terms of scope and duration. All that is granted is the right to *exclude* others from making, using, or selling the claimed invention. There is no affirmative right of a patentee to actually use his or her own invention. To the contrary, there is a wide range of potential restrictions that could constrain, or even prevent, a patentee from utilizing a patented invention. These restrictions include, but are not limited to, regulatory hurdles, the existence of dominating patents, contractual obligations, and financial constraints.

Thus, the patent system is not designed to address issues relating to the actual use of a technology. Rather, the government's involvement in such issues typically comes from legislative bodies and regulatory agencies whose staff is trained in issues pertaining to, for example, health and safety. Because the patent system does not grant an affirmative right to use a technology, the patent system is devoid of considerations pertaining to ramifications resulting from the use of a technology.

E. Purpose of Patents

As noted above, the primary purposes of the patent system are to (a) encourage the investment of time, money, and effort into the pursuit of new products for society, and (b) encourage and facilitate the dissemination of new knowledge throughout the scientific community and the public at large.

The first of these objectives is achieved by the granting of the limited monopoly to inventors. The second object — public dissemination of new ideas — is achieved by publishing the full text of patent applications and issued patents. Thus, when a patent application is published, the complete details of that invention become available to the public so that interested parties can build on this knowledge, thus accelerating the rate of progress.
The legal requirements for obtaining a patent have been carefully crafted so that patents are granted for only a limited period of time, for only the most deserving inventions, and only when the inventor makes public all of the details of the invention.

The specific requirements for patentability are discussed in more detail below.

III. Procedures and Requirements for Obtaining a Patent

In virtually all developed countries (and most developing countries) a patent is obtained by submitting an application to a governmental authority that examines the application to determine whether the application describes an invention worthy of patent protection. Usually the test for patentability includes an assessment by a patent examiner of whether the claimed invention is new, useful and an advance over any similar previously-existing subject matter.

The patent application is also examined to make sure that it contains a complete description of how to make and use the invention.

When people think of the requirements for obtaining a patent, they often think in terms of the characteristics of the "invention" for which patent protection is sought. Although there are very strict requirements for the patentability of an invention, it is important to recognize that the application itself must also meet very stringent requirements if a patent is to be granted. These two sets of requirements — those for the invention and those for the application — are discussed below.

A. Patentability Requirements of an Invention

In the United States there are three primary requirements that an invention must meet in order to be patentable. These are novelty, utility, and nonobviousness. Most foreign countries have analogous requirements.

Although these requirements may sound relatively straightforward, over the years a tremendous amount of case law interpreting them has evolved. A complete treatment of these standards of patentability is well beyond the scope of this paper. However, a brief introduction to these requirements is in order.

Novelty: A patent applicant must demonstrate that his or her invention is new. To be "new" under the patent laws, an invention must not have been available to the public prior to the time when the applicant for patent "invented" it. Thus, if an uninformed researcher were to independently "discover" penicillin today, a patent would not be awarded because, obviously, penicillin is already in the public domain. Therefore, the date of invention is a critical factor in determining if an invention meets the patent law standard of novelty. Similarly, chemicals, cells, viruses or other entities that exist in nature prior to the date of invention *cannot* be patented in their native state because they are not new.

Another factor in novelty determinations is the application date, i.e., the date on which a patent application is filed. In the United States, if a researcher is the first to invent something, the invention does not meet the patent law novelty test if the invention has been available to the public, e.g., in a printed publication, more than a year prior to the filing of a patent application.

Unlike the United States, most foreign countries do not allow any grace period for the filing of an application. For example, Japan and the European Patent Office follow an "absolute novelty" system where patentability is typically barred if a patent application is not filed before any public dissemination occurs. The United States is unique in allowing the 1-year grace period to file an application.

Utility: To be patentable, an invention must be useful. A rejection based on lack of utility is most frequently issued by the Patent Office in situations where the applicant claims what is considered to be an "incredible utility." For example, if an applicant claims that a chemical compound will return people to their youth, that applicant can expect a rejection based on lack of utility. In this situation, the lack-of-utility rejection does not mean that a "fountain-of-youth" compound would not be useful. Rather, the rejection is based on the premise that the claim is so incredible that it is unlikely to be true, and thus the compound lacks legitimate utility.

An applicant faced with a utility rejection can overcome the rejection by providing evidence that establishes that the invention works as claimed. This can occur, for example, in an application that claims a method for curing Alzheimer's disease. Although such a claim may seem incredible, if the applicant can support the claim with convincing data, then the utility rejection will be overcome.

Nonobviousness: The requirement that an invention be "nonobvious" in order to be patentable is the most subjective of the three requirements and is often the most difficult requirement for the applicant to meet. The U.S. patent statutes express this requirement:

> A patent may not be obtained though the invention [satisfies the novelty requirements] if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Stated more simply, if a person trained in the relevant scientific field would have considered an invention to be an "obvious" or "logical" improvement over what already is known to the public, then a patent will not be awarded. One of the critical aspects of this test is that the hypothetical person having ordinary skill in the art is assumed to have knowledge of all relevant publications and public information. Also, this hypothetical person is allowed, at least in some instances, to combine the teachings contained in publications that are widely separated geographically, chronologically, and possibly even in subject matter.

The purpose of the "nonobvious" criterion is to prevent the granting of patents to inventions that are merely predictable and/or small advances over the available art. Thus, it is incumbent on the applicant to demonstrate that the invention was unexpected, highly advantageous, or otherwise more than the next logical step in the course of research. Factors that favor an applicant's assertion of nonobviousness include solving a long-standing problem, failure by others to achieve the same results, and the existence of publications that suggest that the invention would not work.

B. Requirements of the Patent Application

When the Patent Office begins reviewing an application, the patent examiner first makes sure that the application includes the necessary parts. A patent application must consist of a complete description of the invention (the specification) and at least one concise one-sentence statement (a claim) of what the inventor considers to be the invention. Following is a brief synopsis of some of the more important requirements of the patent application.

Enabling disclosure: A patent will be granted only if the subject matter sought to be covered by the patent is described by the applicant in sufficient detail. For a disclosure to be adequate to support a claim, the disclosure must be of sufficient detail so as to enable a person skilled in that field to practice the invention without undue experimentation. Such a full, detailed description is known as an "enabling" disclosure.

If a crucial element of an invention is not disclosed or otherwise known in the art, then the disclosure is not considered to be enabling. This situation can occur when an invention requires the use of novel materials. If a source of the novel materials is not disclosed, then the disclosure is not enabling. For example, if a novel process for producing an antibiotic requires the use of a newly isolated cell, a description of the process would not be enabling if it did not disclose a publicly accessible source of the new cell. For this reason, patent applications for biotechnology inventions often contain references to deposited cultures. The cultures must be placed on deposit at a depository that is recognized by the Patent Office. The conditions of the deposit must ensure that the biological material will be viable and available to the public for a period of at least 30 years commencing when the patent issues.

Claims: Each patent application must include at least one "claim" that clearly sets forth the metes and bounds of what the inventor(s) believe to be their invention. The claim, or claims, appear after the description of the invention. The description is commonly referred to as the "specification." There is no limit to the number of claims that an application may have. The ultimate scope of the patent protection is determined by the claims granted by the Patent Office. Thus, a patent application may contain extensive and broad disclosure; however, any resulting patent protection is limited to the scope of the claim(s) that the patent examiner agrees covers *only* new, useful and non-obvious subject matter.

"*Best Mode*": Under U.S. patent law, if the inventor, at the time of filing the patent application, envisions a preferred way to practice his or her invention, that "best mode" for practicing the application *must* be disclosed in the patent application. This is another way in which the U.S. patent system insures that society receives the maximum benefit from the patent disclosure.

Name Proper Inventors: The patent applicant must identify each individual who contributed to the "conception" of the claimed invention. In this way the patent system seeks to reward those who are most deserving.

Duty of Disclosure: An applicant for patent, and everybody else associated with the prosecution of the patent application, must disclose to the Patent Office everything known to him or her that could have a bearing on the patentability of the claimed invention. This includes, for example, any known prior art references as well as relevant test results. For example, it is not permissible to withhold negative tests or other information that is contrary to the applicant's arguments for patentability. This helps to insure that patents are only granted for inventions that truly meet the statutory requirements.

C. The Patent Examination Process

The Patent Office bears the responsibility of determining, for every application, whether the invention is patentable and whether the formalities of the law have been followed. If and when all the requirements of the law are deemed to have been satisfied, then a patent will be issued.

The Patent Office employees given the responsibility of making these determinations are known as patent "examiners". There are hundreds of examiners in the U.S. Patent Office. Each examiner has at least a bachelor's degree in some scientific field; many examiners have doctorates, are lawyers, and/or have significant work experience.

Each patent application received by the Patent Office is assigned to an examiner who is trained in the scientific field to which the invention pertains. Because of the tremendous number of patent applications received by the Patent Office, it is frequently 8-24 months before an examiner will have an opportunity to review an application. Applications are reviewed in the order in which they are received by an examiner. Once the examiner is satisfied that an application includes the essential parts, the examiner will then determine whether the invention as described and claimed meets the standards of patentability. If these requirements are satisfied and the proper fees are paid, a patent will be issued.

Generally, however, the examiner will find one or more reasons why the invention as claimed is not patentable. The examiner then puts the reasons for these "rejections" in a written communication that is sent to the applicant or the applicant's attorney. This written communication is known as an "Office Action."

The applicant is then given the opportunity to respond to the examiner's rejection(s) with appropriate arguments. If the applicant's response successfully overcomes the examiner's rejection(s), then the claims will be "allowed" and a patent will be issued when the proper fee is paid. If the examiner does not find the applicant's arguments to be persuasive, then the examiner may renew the rejections and/or issue new rejections. This second set of rejections is often made "final." When a final rejection is issued, the applicant will be forced to appeal or drop the case if the examiner's mind is not changed by another response by the applicant.

In addition to making written arguments to overcome rejections, the applicant may also amend the claims so that they more clearly satisfy the requirements for patentability. When all else fails, there are appellate procedures which can be followed in order to have the examiner's decision reviewed.

D. Patents Promote Innovation and Public Disclosure

The novelty, utility, and non-obvious requirements, together with the enabling description requirement (as well as the other requirements of the application), work in unison to ensure that only the most deserving innovations receive patent protection and, once a patent is granted, the public is provided with full access to the teachings of the inventors.

Distilled to its most basic elements, the patent system is simply a means to encourage innovation and promote public dissemination of new ideas and discoveries.

IV. History of Patenting Biological Materials

A review of the history of patenting biological materials can be used to illustrate how the patentability requirements are applied in practice.

When people think of patenting biological inventions, perhaps the current tendency is to think of viable cells, the human genome, or even living animals. Although these technologies now receive a great deal of attention, an examination of patents granted on other types of biological materials over the last few decades helps us to understand how we got to where we are now and, perhaps, where we may be going.

The patenting of inventions utilizing microbial cultures dates back to the early days of the patent law. For example, U.S. Patent No. 634,423 was granted in 1899 for a process for digesting sewage with anaerobic bacteria. The mid 1940's signaled the beginning of heightened patent activity in the microbiological field. Particular emphasis was placed on obtaining patents for the many antibiotics being discovered. The antibiotic streptomycin was covered in U.S. Patent No. 2,449,866 (1948); erythromycin was covered in U.S. Patent No. 2,653,899

(1953); and kanamycin was covered in U.S. Patent No. 2,931,798 (1960).

Antibiotics, such as those covered in the aforementioned patents, are examples of "natural products." As evidenced by the early antibiotic patents, such natural product compounds, produced by microbes, plants and other living entities, have long been patentable. Natural product chemicals include not only antibiotics but also compounds such as anticancer drugs from plants and marine organisms. These compounds, *in their isolated form*, have long been held to meet the requirements for patentability. To wit, the compounds are "new" because they have not previously been available to mankind in their pure or isolated form, they are "useful" because they can be used to treat disease, and they are "unobvious" because, until they were discovered (isolated from their natural environment), mankind had no inkling that a compound with that structure existed and would have useful properties.

As noted above, chemical compounds can *only* be patented if the applicant describes how to make and use the compound. This description is published so that everybody can benefit from this new knowledge.

Proteins are another class of chemical compounds for which patents have been issuing for decades. A protein is a complex, high-molecular-weight organic compound that consists of amino acids joined by peptide bonds. Proteins are essential to the structure and function of all living cells and viruses. Proteins are one of the classes of bio-macromolecules, alongside polysaccharides, lipids, and nucleic acids, that make up the primary constituents of living things.

Like other chemical compounds, a protein can only be patented if, through the hand of man, a previously unknown protein is identified, isolated, and the patent applicant gives full details of how to make and use the protein. Examples of very useful proteins that have been the subject of patents include insulin and erythropoietin.

The general structure and function of another class of chemicals — deoxyribonucleic acids (DNA) — was elucidated in the late 1950s. With this knowledge, researchers were ultimately able to identify, isolate, and determine the function of specific sections of DNA. As with other chemical compounds the patentability of polynucleotides (such as DNA) depends upon whether the chemical compound has been isolated and is distinguishable from any other previously-known compounds. Another important issue when it comes to the patentability of DNA is that the *function* of the DNA must be determined and the patent application must set forth in detail how to make and use the DNA.

From the above discussion it can be seen that the various components of cells have been patented for decades. Also, the use of cells in various processes (such as making antibiotics) has also been patented for decades. However, the patent statutes are silent as to whether viable cells, themselves, can be patented. This issue was settled in 1980, when the Supreme Court affirmed the decisions by the Court of Customs and Patent Appeals (CCPA) in the *Bergy* and *Chakrabarty* cases holding that living cells can be patented. In the Bergy case my father successfully argued in favor of the patentability of "biologically pure cultures." In other words, through the hand of man, these cultures had been made into something that did not exist in nature. The *Chakrabarty* decision acknowledged the patentability of cells that had been genetically engineered to confer upon those cells new and advantageous capabilities.

Although both *Bergy* and *Chakrabarty* involved the patentability of single-celled microorganisms, the language and reasoning of each opinion gave no suggestion that multicellular organisms should be treated any differently. Chief Justice Burger, speaking for the majority in *Charkrabarty*, displayed a willingness to construe the range of patentable subject matter very broadly. Quoting the legislative history of the current Patent Act, the Chief Justice stated, "Congress intended statutory subject matter to "include anything under the sun that is made by man." The Court also noted that, as a matter of statutory construction, the patent statute's use of broad terms to define patentable subject matter is evidence that 'Congress plainly contemplated that the patent laws would be given wide scope.'

Another example of a broad interpretation of the subject matter provision of the patent act is the 1985 PTO Board of Appeals ruling that plants can be patented. In reaching this result in *Ex parte Hibberd* the Board emphasized that Congress intended the patent statutes to be construed expansively.

In 1987 the United States Patent Office announced that it would grant patents on *non-human* multi-cellular living organisms, including animals. The Patent Office announcement came less than a week after the Patent Office Board of Patent Appeals held in *In re Allen* that polyploidy oysters are patentable subject matter. The *Allen* decision and subsequent Patent Office policy statement marked the end of a longstanding Patent Office policy whereby patent claims to multicellular animals were automatically rejected on the grounds that animals were not patentable.

In 1988 the U.S. Patent Office issued a patent for the "Harvard Mouse," a mouse that had been genetically modified to enhance its usefulness in research to find causes and cures for cancer.

The current policy of the U.S. Patent Office is to not grant patents on "humans." For example, U.S. Patent and Trademark Office, "Notice: Animals--Patentability," 1077 Official Gazette U.S. Pat. and Trademark Off. 8 (April 21, 1987) states:

> The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101. A claim directed to or including within its scope a human being will not be considered patentable subject matter under 35 U.S.C 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation 'non-human' to avoid this ground of rejection.

> Also, §2105 of the Manual of Patent Examining Procedure (MPEP) states as follows:

> If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter. Furthermore, the claimed invention must be examined with regard to all issues pertinent to patentability, and any applicable rejections under 35 U.S.C. 102, 103, or 112 must also be made.

The MPEP does not provide a definition for "human being;" however, testimony by various Patent Office representatives has shed light on the PTO policy. For example, a USPTO official testified to the President's Council on Bioethics:

> When a patent claim includes or covers a human being, the USPTO rejects the claim on the grounds that it is directed to non-statutory subject matter. When examining a patent application, a patent examiner must construe the claim presented as broadly as is reasonable in light of the application's specification. If the examiner determines that a claim is directed to a human being at any stage of development as a product, the examiner rejects the claims on the grounds that it includes non-statutory subject matter and provides the applicant with an explanation. The examiner will typically advise the applicant that a claim amendment adding the qualifier, non-human, is needed, pursuant to the instructions of MPEP 2105. The MPEP does not expressly address claims directed to a human embryo. In practice, examiners treat such claims as directed to a human being and reject the claims as directed to non-statutory subject matter. (Testimony of Karen Hauda on behalf of USPTO to the President's Council on Bioethics, June 20, 2002, *http://bioethicsprint.bioethics.gov/transcripts/jun02/june21 session5.html)*

Current Patent Office policy, then, is that any claim that can reasonably be interpreted as "directed to" or "encompassing" a human being, and any claim reaching beyond "nonhuman" organisms to cover human organisms (including human embryos), must be rejected.

In this regard it can also be noted that, since 1996, Congress has annually prohibited federal funding of research in which human embryos are created or destroyed — and this legislation defines a human embryo as a "human organism." In December 1998 testimony before the Senate Appropriations Subcommittee on Labor/HHS/Education, a wide array of expert witnesses — including NIH Director Harold Varmus — testified that this legislation does not forbid funding research on embryonic stem cells, because a human embryo is an "organism" but a stem cell clearly is not (see S. Hrg. 105-939, December 2, 1998). That same conclusion was later reached by HHS general counsel Harriet Rabb, in arguing that the Clinton administration's guidelines on stem cell research were in accord with statutory law; this same legal opinion was accepted by the Bush administration when it issued its more limited guidelines for funding stem cell research (Legal memorandum of HHS general counsel Harriet S. Rabb, "Federal Funding for Research Involving Human Pluripotent Stem Cells," January 15, 1999).

Thus, under current legislation, although "humans" (including embryos) are clearly not patentable, stem cells are patentable (assuming that, as claimed, the stem cells were produced by "the hand of man," and that they meet the other requirements for patentability).

V. Application of the Patent Laws to Emerging Technologies

Many of the issues being raised currently with regard to the patenting of, for example, the human genome and stem cells bring to mind discussions that took place at least as far back as 1980 when the Supreme Court ruled that living microorganisms could be patented. At that time, some noted with alarm that if microbes could be patented then before long surely there would be patents on mice, chickens, and other animals. This scenario has obviously come to fruition; what about the other concerns that have been expressed about patenting biological material? It seems that those concerns can be categorized as follows: economic, legal, and philosophical/ moral. Each of these is discussed below.

A. Economic Issues

It has been argued that the granting of patents on biotechnology inventions is bad for economic development because, for example, patents (in particular broad patents) can stifle research; ownership of genomic information could become concentrated among a few powerful companies; and richer nations and/or companies might plunder the resources of the less powerful.

Certainly an ongoing debate exists with regard to the latter; however, issues relating to the exploitation of natural resources are now primarily being addressed in the context of international trade negotiations — including the Biodiversity Treaty. Thus, questions pertaining to the use of natural resources appear currently to be mostly international trade issues rather than domestic patent law issues. Ultimately, one would hope that a fair balance can be struck between promoting the development of health advances on the one hand and, on the other hand, protecting the natural resources of all countries, including developing nations. This should include providing appropriate compensation for those countries (or other entities) that serve as the source for raw materials that are developed into, for example, valuable medicines.

In this regard, it may be worthwhile to note that the U.S. patent system appears to have served us well in terms of providing a legal framework in which new medicines can be developed. In a 2001 Statement before the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies, Maria Freire, the Director of the Office of Technology Transfer of the National Health Institute stated:

> Patents provide the right to exclude others from making, using, selling, offering for sale, or importing a new invention for the life of the patent. This is society's reward to the owner for teaching others how to make and use the invention claimed in the patent. In the biomedical field, patents are extremely valuable to companies, particularly small companies. They provide a means of securing investment income by establishing the company's preeminence in a particular area of technology. Parties interested in practicing an invention in which they have no ownership may obtain rights to the invention by entering into a licensing agreement with the patent owner.
>
> * * *
>
> As this Subcommittee well knows, new drugs and vaccines are costly to develop, and companies are unlikely to invest in further research and development without some promise of future product exclusivity.

Similar views have also been expressed by the Biotechnology Industry Organization (BIO), which stated in a letter dated March 22, 1999 to the National Bioethics Advisory Commission:

> BIO strongly supports the incentives provided by intellectual property rights to spur both academic and private company research on stem cells and other biomedical technology. We believe that academic scientists can access research tools to facilitate basic research.
>
> However, once a research project becomes commercially situated, scientists should gain the protections of the intellectual property system to reward high-risk investment and spur product development. Such protections also act as a spur to further innovation and competition.
>
> * * *
>
> Strong patent protection is essential to the discovery and development of new medicines. While it rewards risky investments, it also stimulates competitive innovation.
>
> * * *
>
> There may be no industry more sensitive to patent protection than the biotechnology industry.
>
> The rate of investment in research and development in this sector is higher than in any other industry. Any law which undermines the ability of biotechnology companies to secure patent protection undermines funding for research on deadly and disabling diseases. Also, if the ability to patent government inventions is undermined, it will diminish the ability of biotechnology companies to develop basic research advances from government scientists into products for patients. Capital will not be invested in biotechnology companies if they are not able to secure intellectual property protection to recoup their substantial investments to research and develop a product for market.

Our industry's position on patents follows from one simple fact about the biotechnology industry: most of our firms fund research on deadly and disabling diseases from equity capital, not revenue from product sales. Without investors taking the risk of buying the stock of our companies, much of our vital research would end. Almost without exception, our industry cannot borrow capital. Our principal — and for most of our companies the only source of capital — is equity capital.

Intellectual property protection is critical to the ability of the biotechnology industry to secure funding for research because it assures investors in the technology that they will have the first opportunity to profit from their investment. Without adequate protection for biotechnology inventions, investors will not provide capital to fund research. There is substantial risk and expense associated with biotechnology research and investors need to know that the inventions of our companies cannot be pirated by their competitors.

Some have argued that gene sequences, and especially gene sequences identified utilizing public resources (i.e. NIH or Universities), should not be patented and, instead, should be made available to the "public." In these cases, the role of patents in expediting public disclosure is perhaps less critical in view of the tendency for such researchers to publish their results. However, a careful analysis of these situations reveals that patents can actually play a crucial role in the effective commercialization of this technology and the equitable distribution of profits which may result from such commercialization.

Take, for example, the NIH discovery of a new gene or protein with potential usefulness as a therapeutic agent. The cost of bringing a new pharmaceutical to market can be hundreds of millions of dollars. The NIH does not have the expertise or resources to take this new gene or protein all the way from the laboratory to the market place. Therefore, the technology must be developed by an outside entity. In order for that outside entity to have a realistic chance of recouping its investment it is critical to have a limited period of exclusivity for that product. Without any prospects for patent protection, a new technology is far less likely to be developed. Of course, as discussed above, patent protection is granted *only* if the gene or protein is new, non-obvious, its utility is determined, and the patent applicant provides complete details of the invention.

Patents can also play an important beneficial role in equitable distribution of profits from university technologies. In this regard, consider the process of development of university technologies prior to the use of patents. At universities that did not seek to protect their intellectual property it was common practice for big companies, and other private entities, to directly contact researchers who had promising technologies. Often, at little or no cost, that company could have immediate and complete access to valuable technology. When that company developed the technology, no compensation was given to the university. Rather, that company reaped a windfall from publicly funded research. By contrast, if the technology is patented by the university, the company will be required to obtain a license for the technology and share its profits with the university. Typically, the funds paid to the university will be distributed among the inventors, the University department from which the invention came, and the general funds of the university. In this way, the taxpayer's money that originally went towards university research has paid dividends in the development of the technology as well as the enhanced funding of the university.

The proponents of biotechnology patents also argue that there is no reason to believe that this type of research will cease to be conducted if the patent system does not protect property rights. Instead, scientists will be forced to protect their rights by keeping the results of the research as trade secrets. Such secrecy is contrary to the rapid dissemination of new and useful ideas, which the patent system is designed to encourage. Thus, although some have expressed concerns about the impact of patents on economic development, it appears that the economic benefits from a properly-functioning patent system far outweigh any potential negative impact attributed to the limited period of exclusivity provided by patents.

B. Legal Issues

Some have argued that patents on biological materials are contrary to the U.S. statutory provisions relating to patents. This argument appears to have little merit because, as discussed above, the patent statutes do not specifically address the patentability of biological materials, but the Supreme Court, Congress, and others within the legal system have clearly found that the patent system, including the issuance of patents on living cells and animals, currently operates in accordance with its constitutional mandate and legislative framework.

As noted above, the U.S. Patent Office has stated that it will not grant patents on humans. With regard to animals, no animal, or any other subject matter, can be patented in its naturally occurring form. To be patentable, an invention must be new. A microbe, plant, or animal, *as it exists in nature* is not new. Furthermore, for the subject matter to be patentable, the characteristic which makes the subject matter new, i.e. different than what exists in nature, must be supplied by human inventive input. Thus, for any invention to be patentable it must involve the "hand of man."

In addition to the novelty requirement which precludes the patenting of subject matter as it exists in nature, the patent laws have additional stringent requirements that prevent the patenting of subject matter that is not a substantial advancement over previously known technology. The most important of these is the requirement that an invention be "non-obvious" in order to be patentable. Thus, in order to be awarded a patent, it may not be enough to simply isolate a new protein (or other chemical molecule). The new protein must be non-obvious. Unusual and/or unexpected advantageous properties are characteristics that can help establish that a new material is unobvious. Also, difficulties in obtaining the protein may make it unobvious. These requirements of novelty, non-obviousness, and involvement of the "hand of man" apply to *every* invention for which patent protection is sought.

A careful inspection of patents that have issued for chemical compounds, animals, microbes, and plants would reveal that in each case the inventors have provided society with something that is not only new but is even non-obvious compared to anything previously made by man or known to exist in nature.

As discussed above, a further requirement of the patent law is that the patent applicant must provide a description of the invention in such detail that a person skilled in the art of the invention, reading the description, can make and use the invention without undue experimentation. This requirement is at the heart of the patent system because it ensures that, if a patent is granted, the public will be able to learn from the invention, improve upon the invention, and when the patent expires, practice the invention without any patent restriction.

Thus, although it would certainly be possible for Congress to modify the patent laws to, for example, prohibit the patenting of animals, in the absence of such new legislation, the patent system appears to be operating entirely in accordance with the current relevant laws.

C. Moral and Philosophical Issues

Even among those who acknowledge that the patent system is operating in accordance with the U.S. constitution and the applicable laws, and appears to do more economic good than harm, there can be misgivings about patenting of biological materials. For example, one rationale sometimes heard from those who oppose biotechnology patents is that people should not be allowed to "own" life forms or the basic chemical molecules that are fundamental to life.

However, the grant of a patent is not the grant of an ownership right; rather, the grant of a patent only gives the patent holder the right to *exclude* others from making, using or selling the patented subject matter for a limited period of time. The grant of a patent does not give the patent holder the right to use the invention. The right to use the invention may be blocked or restricted by federal health, safety, or environmental regulations; by another's dominating patent; by contractual obligations; by state laws; by international treaties; and by a host of other impediments and/or safeguards that exist within our society.

Also, as discussed above, patents are only granted for inventions that meet the strict novelty, utility, and non-obviousness requirements. These requirements preclude the granting of patents to things as they exist in nature. The "hand of man" must be involved before there is a possibility of issuing a patent.

Some have stated that the decision regarding the patentability of animals, for example, carries with it tremendous moral and ethical consequences and, therefore, should not be left solely to the discretion of a single governmental agency. Among the concerns expressed are: potential suffering of animals used in genetic engineering research, monopolization of genetic codes by corporations, and the end of the 'natural world' as the result of wholesale genetic manipulations of many species. For those who are familiar with the patent system and how it is implemented, it is clear that these concerns should be addressed in a forum that allows input from groups with diverse points of view representing a fair cross-section of the population. The patent application process simply does not provide an appropriate forum to fully consider such issues.

Congressional hearings provide interested parties an opportunity to present their views and have these views considered in the context of what is best for society as a whole. For example, it has often been noted that genetic engineering is really not different from selective breeding except that it allows researchers to reach the desired result more quickly and with less trial and error. It can be argued, therefore, that genetic engineering technology may actually be more humane to animals than the widely-accepted practice of selective breeding because the results are much more predictable and because the technology can be used to improve the quality of existence for these animals.

As the Supreme Court noted in *Chakrabarty,* the ethical and moral ramifications of legislation are beyond the purview of the judicial system (including the Patent

Office). The Court stated that these considerations are "matter[s] of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives."

Accordingly, it seems that informed public debate, including the legislative process, is the most appropriate means for exploring the issues (and legislating where necessary) concerning the conduct of biomedical research and the introduction of new biological technology into our society.

VI. What Lies Ahead?

As discussed above, the patent system appears to operate in accordance with current legislation. Furthermore, the patentability of biological inventions involving, for example, proteins, genes, microbes, stem cells, animals, and humans appears to be fairly well settled. This does not mean, however, that no further debate is likely or warranted. To the contrary, there are still efforts by some to introduce legislation that could alter the definition of what is patentable under the patent laws. Currently, it does not appear that any such efforts are likely to be successful in the foreseeable future.

It is also conceivable that the patent laws could be amended to require some sort of morality requirement for patentability. In my view, any such modification to the patent laws would be ill-advised. Such a requirement would, by necessity, be very subjective and the Patent Office, with its current personnel and training is not equipped to administer such a requirement. Such considerations are best examined in a more open forum, such as the legislative process or in regulatory reviews, where all relevant aspects can be fully considered. Even in the absence of new legislation, however, new technologies may rekindle the now-familiar debate. For example, potential gray areas of the law include animals that have been modified to include a few human genes so they can produce a human protein or antibody. Another example is human/animal "chimera" (an embryo that is half human, half animal). These situations have already received some initial consideration by the Patent Office. The Patent Office has already granted patents on the former (see U.S. patent nos. 5,625,126 and 5,602,306). It has also thus far rejected patents on the latter, the half-human embryo (see Biotechnology Law Report, July-August 1998, p. 256), because the latter can broadly but reasonably be construed as a human organism.

VII. Conclusion

Over the years, the patent system has often served as a lightning rod attracting attention from individuals concerned about new technologies. Although new technologies often become the subject of patents, a thorough understanding of the patent system leads to the conclusion that concern about new technologies would best be expressed in the context of the legislative process or with agencies that monitor and regulate research and the implementation of technology. Although the issuance of a patent may seem to reflect a governmental "stamp of approval," the truth is that a patent provides nothing more than the right to *exclude* others, for a limited period of time, from using the patented technology. Furthermore, patents have over the years, proven to be an effective method for disseminating information about new technologies.

Thus, while eliminating patent protection for certain technologies may have a certain symbolic value, it would appear to have no impact on the possible use of the technology and may well force those in the field to rely on trade secrets to protect their interests. Such a development would not be conducive to a full and open debate about the merits of the underlying technology. A more sensible approach is to facilitate public disclosure of these technologies through the use of the patent system while, at the same time, utilizing regulatory and legislative processes to carefully monitor and regulate research and the implementation of new technologies to reap the benefits of human ingenuity while minimizing the risks associated with these new technologies.