

The moral significance of intellectual property regulation

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ABSTRACT

Fundamental ethical principles provide guidance for the protection and wider use of intellectual achievements. As regarding established rules for claims of authorship in scientific publications, use of intellectual property is not a matter of providing an open unregulated access but to honor the intellectual achievements while providing an avenue to wide application for promotion of innovation to the benefit of society. This is done through a balancing of different interests. In this article I examine some of the basic principles for this balancing task. A special concern in the discussion about intellectual property regulation has been the need to fit new scientific and technical innovations within the changing moral landscapes of different countries. Innovations must not offend what is considered "public order". I put this claim into perspective by demonstrating that this value laden concept needs to be adjusted in accordance to changing moral landscapes that often follow when new innovations become part of main stream technology and provide significant benefits.

OPENNESS ON FAIR TERMS FOR DISSEMINATION OF KNOWLEDGE AND INNOVATION

In popular views it may be believed that patenting and intellectual property regulation is a way of hiding new findings and methodological development in various areas from others. The contrary is in fact true and is of great moral significance. The following story told by a colleague in molecular biology at a Swedish university may illustrate the point. He was visiting a large biotech company and on his tour around the facility he saw that they used a new and very innovative method for analysis of biochemical compounds. He hadn't seen it before but it was a method that would be of great value for use also in his own laboratory. However, the company was big and didn't really bother about a patent in this case. His comment to his guide was: "Why don't you patent this method so that we can use it also in my lab"? Patenting is in this sense an instrument for providing open access to innovations, with the important addition *open and regulated access*.

Openness is a cherished value also in academic life with recent requirements from funding agencies to provide

open access of publications. It is important from a scientific point of view since a central requirement in science is that claimed results must be reproducible. Another scientist with sufficient skills must in principle be able to replicate the findings using the same kind of material and the same methods. However, also here it is a matter of open but not unregulated access. The same holds for sharing of data that have been used for the research. In biomedicine, sharing of data and bio-specimens is essential for the discovery, new knowledge creation and translation of various biomedical research findings into improved diagnostics, biomarkers, treatment development, patient care, health service planning and general population health. There is a growing international agreement on the need to provide access to research data sets to optimize their use and fully exploit their long-term value^{1,2,3}.

Ideally, data should be made widely available to the most inclusive and ethically responsible research, but there is often resistance by institutions and individuals who fear that they will not receive recognition for their investment in collecting the data. Data is not freely floating around to just be picked. It is the result of systematic efforts requiring scientific accuracy regarding selection and use of methods, as well as resources and time. This feature is recognized in the existing research ethics rules and guidelines for authorship in academic journals. The International Committee of Medical Journal Editors recommend that authorship should be based on "substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work" (also known as the Vancouver guidelines for authorship)⁴. Regarding sharing of and access to data as well as biospecimens the following ethical principle have been suggested as guidance to the research community⁵.

1. Freedom of scientific enquiry: custodianship should encourage openness of scientific enquiry, and should maximize data and bio-specimen use and sharing so as to exploit their full potential to promote health.
2. Attribution: the intellectual investment of investigators involved in the creation of data registries and bio-repositories is often substantial, and should be acknowledged by mutual agreement.
3. Respect for intellectual property: the sharing of data and biospecimens needs to protect proprietary information and address the requirements of institutions and third-party funders.



From a laypersons perspective these principles are reflected also in intellectual property law⁶. A patent acknowledges the principle of attribution but protects at the same time openness and freedom of scientific enquiry. The exclusive right to exploit an invention is referring only to commercial use, leaving academic research and intellectual exploitation open for anyone. It may be seen as a vehicle for innovation and as a stimulation for open competition to look for alternative means to solve a problem, ideas that are intrinsic to science as well. Openness, whether through publication or patenting, is arguably also something expected by funding agencies, both governmental and private. They don't grant money for research in order for scientists to hide the results in the drawer. They should be used as widely as possible for innovation and social benefit.

PUBLIC ORDER AND MORALITY

There is a well-known article in patent law pointing at the moral significance of a patent approval process. In the Swedish Patent Act (1967:837, 2020:541) this is formulated in Chapter 1, Article 1c, laying down that "a patent is not granted for an invention where the commercial exploitation would be contrary to public order or morality". Within the field of biotechnology and life science this has implied some challenges related to find out where to draw the line between what is in accordance with public order and morality, and what is contrary. It is well known that the moral landscape is in constant change in all societies, more and more rapidly due to new communication and information means that don't respect any national borders. In biotechnology and life science the situation is accentuated with scientists constantly breaking barriers on what was seen as possible. There are several stories where new discoveries have led to intense discussions about moral acceptability, and requests for legislation, including related to intellectual property regulation.

As described in detail by Marianne Levin, based on a report from the sixth Framework project in EU *Stem Cell Patents: European Patent Law and Ethics*, the exceptions regarding patentability based on the above clause have to be based on national constitutional and culturally accepted value systems.⁷ It is regarded as self-evident that in a political democracy, people's values play an important role. Not only all legislation, but also other policy and regulatory decisions, presuppose some degree of anchorage in the values of the people. Despite this, values do not in themselves constitute good arguments, and from an ethical point of view, it is problematic to take these for granted. The reason is that one sometimes changes one's opinions after having acquired more information about the facts, or having perceived the kind of value conflicts which arise, when some value which one esteems is achieved while other values are denied. One perhaps discovers values which had passed unnoticed and undesirable consequences which had not been anticipated. One tends therefore to agree with George Henrik von Wright's idea that informed preferences should be taken more seriously than the preferences we actually happen to have at the

moment.⁸ "To come into possession of, or experience some X which we wish, increases our welfare provided that we would wish this X if we were informed about the causal relations and consequences which hold both for the totality of which X is part and the totality where not-X is included instead of X" (*ibid.*, 7). von Wright speaks in this connection about people's individual preferences, but it ought to be possible to apply this reasoning also to collective political decisions, for example those which apply to the balancing of values at stake in association with regulation of life science research and biotechnologies.

An intrinsic requirement for moral assessment is that conclusions and advices are based on a close understanding and acknowledgement of scientific facts and realistic considerations of contexts for research or practice where ethicists and lawyers work closely together with scientists and practitioners. This implies that foresight analyses where current knowledge and practices are extrapolated in order to speculate about and discuss likely future scenarios is of limited value since there is no factual evidence available. There is also a tendency that foresight analyses focus more on disadvantages than advantages and that they are ultimately not able to balance ethical reflections between Dystopia and Utopia alternatives. New emerging technologies face specific problems due to their complexity or novelty. Gene therapy, preimplantation genetic diagnosis, whole genome sequencing or gene editing may be candidates in kind. They have all stirred intense ethical discussions when they first were presented in scholarly journals and at scientific conferences, or reported in public media. Some early research applications with these technologies were indeed premature and should have awaited better evidence but, after some progress and more scientific evidence about benefits and risks, most of them will belong to main stream medical science.

Gene therapy is an example of a promising new technology developed forty years ago. It met with quite some resistance, not the least from religious representatives. Some warned against Gene therapy as a way of "Playing God".⁹ The term may be interpreted in two ways. First, it may convey an idea about the power of genetic intervention itself. It was claimed in the debate, during the late 1970's and the beginning of 1980's, that scientists now were on the threshold of understanding how the fundamental machinery of life works.⁹ What was earlier



objects of awe and wonder were now perceived as objects under human control, one was "tampering with the basic building blocks of life". Second, it may convey an idea that genetic intervention may create new life forms, the consequences of which can neither be foretold, nor controlled. The objection of "playing God" could, however, easily be turned in another direction, as was done by a father, three of whose children suffered from a sickle disease. He said: "I resent the fact that a few well-meaning individuals have presented arguments strong enough to curtail the scientific technology which promises to give some hope to those suffering from a genetic disease. I have faith to believe that genetic therapy research, if allowed to continue, will be used to give life to those who are just existing... I, too, would like to ask the question, who do we designate to play God? Aren't those theologians and politicians playing God? Aren't they deciding what's best for me without any knowledge about my suffering?"¹⁰ Forty years later there are several clinical trials with gene therapy ongoing, in particular for rare diseases where there are few or no treatment alternatives available. The technology is now moving into main stream medical science governed by ordinary regulatory frameworks for clinical trials, despite the fact that in the beginning it was by many conceived as being against "public order and morality".

One area of life science research that has been focus for intense discussions on patentability is the production and use of human embryonic stem cell lines. According to the referred article of the Swedish Patent Act "the use of human embryos for industrial or commercial purposes" is considered as contrary to public order and morality and, accordingly, excluded from patentability. This interpretation is reiterated in the official information from the Swedish, Intellectual Property Office (PRV): "Methods which use human embryos, such as the production of embryonic stem cells, are ... not patentable".¹¹ A common argument for excluding human embryos from patentability is that the recovery of stem cells from the embryos with necessity implies that they are destroyed, something

that would constitute a violation of the respect for life.¹² The argument is, however, dubious for the following reasons. Recovery of stem cells is only done using left-over cryo-preserved embryos in association with in vitro fertilization. These embryos will be discarded any way and are treated as hazardous biological waste in the fertility clinics. They are voluntarily donated by the couples themselves who provide a written informed consent. To donate them for research and medical purposes is seen by these couples as a good alternative to just destroy and throw them away. It is also a fact that many countries, including Sweden, permits research on fertilized eggs up to day 14 of the development, a practice that also implies the destruction of the embryos (see LGI 2006:351).

A recent study among the Swedish general population showed that even those respondents who regarded the embryo as "potential life" were positive to the use of surplus embryos for a good medical purpose.¹³ The context here was the use of human embryonic stem cells for the development of Advanced Therapy Medicinal Products (ATMP) in order to treat patients with Parkinson's disease. As for now, the etiology of Parkinson's disease is still unknown. There are no disease modifying therapies available for patients so therapy focuses on symptom relief by compensating for low brain dopamine levels. Commonly, patients' daily lives are increasingly affected over time by symptoms such as tremor, slow movements and balance problems. It is common to develop non-motor problems like depressive symptoms and later dementia. As the symptoms get worse with time, medicines are often given more frequently and device-aided therapies are introduced. It is not uncommon that patients suffer from side-effects of treatment, such as dyskinesia or behavioral problems. Parkinson's disease is one of the first examples of this kind of cell therapy that now is close to clinical application.¹⁴ In general, respondents were positive towards the usage of embryonic stem cells to treat patients with Parkinson's disease, but the usage were conditioned and specific terms were demanded. Informed consent from both donors were required

and delicacy and sensitivity when working with embryos were needed.

It seems, in this case, as in many other instances related to the new developments in life science exemplified above, that views on "public order and morality" changes when there are clear (medical) benefits attained. Technological developments and value changes in society form the basis for the establishment of new social conventions. One may believe that saying no to new biotechnologies is the morally safe way to go but if important benefits and risks (e.g., related to staying at the level of currently available insufficient treatment) are at stake one is equally responsible both when saying no and saying yes, alluding here to von Wright's argument earlier. Taking these studies into regard the time seems to be ripe for reforming the patent law in order to stay better attuned to "public order and morality", assuming that it is the Swedish public order and morality that shall be taken into regard. It is the responsibility of legislators, judicial authorities and policy makers to closely monitor both the factual circumstances of new life science technologies and the constantly changing moral landscape of salient values. We cannot expect that they will always make the right decision, but we do expect that they will consider all relevant aspects of a case and that they will take and weigh up the arguments in their final judgement in a way which is reasonable with reference to the importance of the issue and the consequences which follow from their judgement.

It is clear also that, in this field as in many other developments of medical treatment, the involvement of the biotech industry and pharmaceutical companies is necessary in order to bring a research innovation all the way from the lab bench to clinical use. Even if academic partners may not be interested in seeking patent protection of their achievements it is essential also to make sure that this road is not closed for commercial partners approached later in the development process for collaboration downstream in order to attain a real patient benefit at the end.

BALANCING THE SCOPE

A central component in all ethical and legal discussions is the need of reaching a balance between different values at stake and between different interest held by different stakeholders. The requirement of balancing is well represented in the premises for ethical review of both animal and human subjects' research. According to the Swedish Act (2003:460) on ethical review for research involving human subjects the task of ethical review boards is to balance the scientific value of a research project against the risks which people acting as experimental subjects may run by participating in the experiment. I have elsewhere in some detail discussed the need of balancing privacy concerns against the interests related to providing new and improved treatment opportunities through medical science and will not reiterate that here.¹⁵ As described above, scientific progress and innovation in the field of life science requires a wide access to both research data and personal data. Since human rights are often

referred to in connection to expressing the need to protect human interests in association with the use of personal data in life science development I will just make one point focusing on the balancing of privacy/integrity and the interests of making progress in medical science.

The use of personal data should stand in agreement with the European Convention for the Protection of Human Rights and Fundamental Freedoms, the Social Charters adopted by the Union and by the Council of Europe, the Charter of Fundamental Rights of the European Union (2010/C 83/02). The right of each individual to integrity within the fields of medicine and biology implies, according to these premises, a free and informed consent according to the procedures laid down by law (Article 3). The right of each individual to the protection of personal data concerning him or her is recognized (Article 8), implying that processing of such data requires consent of the person concerned or some other legitimate basis laid down by law, e.g., as laid down in GDPR, with reference to public interest. In addition to these autonomy rights, it is also acknowledged that the Charter of Fundamental Rights of the European Union also lays down rights of each individual to social security benefits and social services in cases of illness (Article 34), the rights of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices (Article 35). In this context the steering principles laid down in the United Nations Declarations of Human Rights (Article 27) also apply:

1. *"Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.*
2. *Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."*

Thus, balancing of different interests and rights need to be reflected in legislation and legal practice. This is well recognized in the intellectual property legislation, as described above. At one of the extreme ends, the intellectual property holder may want as far-reaching exclusive use of a product or method to be patented as possible. At the other end, society, e.g., patients and scientists, want benefits to be as freely available as possible. One example of this conflict of interests is the discussions related to use of human embryos for research. The example also highlights the need, both in ethical and legal analyses, to have a good grip on the factual basis.

The European Group on Ethics in Science and New Technologies (EGE) is an independent ethical advisory body of the President of the European Commission, founded in 1991. The EGE reports to the President and to the Commissioners as a whole. In 2002 the EGE evaluated the ethical aspects of patenting inventions involving human stem cells.¹⁶ They argued that isolated stem cells, which have not been modified, do not, as products, fulfill

the legal requirements to be seen as patentable. Induced pluripotent adult stem cells may fulfil this requirement since they have been genetically modified. Genetical modification was one example given by the EGE. EGE claimed that one should distinguish among: (a) “stem cells freshly derived from an organ or tissue which have not yet been subjected to any modification and which are capable of being propagated as stem cell lines,” (b) “unmodified stem cell lines which refer to cultured lines of cells which have been propagated originally from freshly derived stem cells and which have not been modified in any other way. . .,” and (c) “modified stem cell lines which refer to cultured lines of cells, propagated from stem cells or stem cell lines, which have been modified either by genetic manipulation, or by treatment that causes the cells to differentiate in a particular way” (*ibid*). Only the last kind of cells should be patentable according to EGE.

Genetic modification, as in the production of induced pluripotent adult stem cells, represents indeed a major scientific achievement and something that may be acknowledged in intellectual property protection. However, in discussions with stem cell scientists it became clear that already the act of producing a viable stem cell line requires extraordinary scientific skills and effort.¹⁷ Also isolated embryonic stem cell lines are results of modification. The only “unmodified” human stem cells are those still present in the human body or embryo. Embryonic stem (ES) cells are isolated from in vitro fertilized (IVF) embryos that have been cultured in vitro up to the blastocyst stage. If used for infertility treatment, such embryos are transplanted into the uterus of a woman. If used for the derivation of an ES cell line, the blastocysts are explanted into a special culture medium and cultured in vitro for an extended period of time, generating a novel cell type that is not part of the blastocyst. Already, the act of placing a cell into a culture medium implies modification.¹⁸ The isolation process does not select for pluripotency, just for survival, with pluripotency being a useful side product of the procedure. The result of adaptation to tissue culture is the outgrowth of cells that have no equivalent to cells in the embryo. Thus, an ES cell basically represents a cultural artifact. Based on these facts it has been argued that isolated embryonic stem cell lines may carry sufficient novelty, inventive step and potential for industrial application and be in principle patentable as products, besides patentability of the methods developed for their isolation and proliferation (*ibid.*).

An important feature of intellectual property law is the requirement of balancing rights of exclusive use and the importance of producing common benefits for society. It is important to note then that patentability does not necessarily lead to broad patents. An example of this may be seen in relation to the WARF patent application. The United States Patent and Trade Mark Office issued a broad patent on December 1, 1998 claiming patent on primate ES cells, including human and on March 13, 2001, a second patent focusing on hESC.¹⁹ The origins of the cell lines were two nonhuman species of primates, but the claim granted covered a larger group of primates, including humans. hESC made in another country become

subject to U.S. patent law if they were to be imported into the United States. As described above, the fundamental principle of a patent is to protect reasonable commercial claims and inventive achievements as a means to promote technological development and application of research into different sectors of society. The two WARF patents violated this principle by granting claims with an unreasonable scope leading to a situation that, in fact, may be detrimental to stem cell research. This story underlines the importance of balancing on behalf of patent authorities.

CONCLUSION

Ethical consideration is about balancing different values and interests against each other. Intellectual property regulation is a vital means for open access and innovation, provided that one adheres closely to the scientific factual context and to the changing moral landscapes of societies. Open, but not unregulated access is the way forward.



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