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THE STRUGGLE AGAINST THE PATENTING OF A GENE

by

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Overview

Appropriation of a living agent by means of a patent is the subject of a debate which is characterised both by well-meaning intentions and by lack of knowledge of the subject. The debate reached its climax in France when the European Patent Office (EPO) granted Myriad, an American company, a monopoly for genetic diagnosis of breast cancer. Thanks to Jacques Warcoin, this patent was withdrawn in June 2004 by the EPO's Opposition Division, to the satisfaction of those who saw in this retraction the refusal to allow the appropriation of living beings, objects or human genes. Jacques Warcoin shows that this struggle had already been lost a long time ago. He analyses the fundamental elements at stake in this affair which turned out to be economic : the patent system, invented in the middle of the nineteenth century to reward inventors, has been transformed into a formidable weapon which companies have used for their own economic strategies.

TALK : Jacques WARCOIN

I started in the Regimbeau law firm thirty-three years ago, with a background in chemistry. Very soon afterwards**,** the firm was invited to work in patents in microbiology, and my superiors asked me to manage the project : *« You'll see, it's a bit like chemistry »*. I accepted and quickly realised that it had nothing whatsoever to do with chemistry… Thanks to the distinguished professors who were the people with whom I was dealing, I became increasingly familiar with this field, to the point that when biotechnologies arrived in 1979, I found myself writing the first patents. Today, I have seven co-workers specialising in biotechnologies, and we have been involved in practically all the important developments in this field over the last few years, both in France and in Europe. The Myriad affair was the one which attracted the most media attention.

The breast cancer gene

It all began in 1989. Marie-Claire King, an American scientist, was convinced that in some cases, breast and ovarian cancer were due to genetic disorders. She created the Breast Cancer Linkage Consortium which gradually brought all the research groups working in this field together.

In 1993, the Breast Cancer Linkage Consortium discovered that having the chromosome gene BRCA1 (*BReast CAncer 1*) as well as other close markers (ie. the specific DNA segments) predisposed the individual to human breast cancer.

It was at this point that the American group, Mark Skolnick, thought that the consortium's work was proceeding quickly enough and decided to create a company, Myriad, whose aim was to identify the responsible gene as quickly as possible. A race then began as the consortium was not prepared to be overtaken by another group.

Myriad's patents

From 1994, Myriad filed its first patent request for the BRCA1 gene. Unfortunately, a part of the patent was missing and, most importantly, sequencing included about fifteen errors, relatively little by comparison with the gene's six thousand nucleotides, but it was to be extremely important as far as the rest of the story was concerned.

Myriad filed a second, third and then fourth patent request, each time with new amendments. It was only at the fifth attempt that all the errors were corrected. Shortly before this fifth parent request was registered, Myriad published its findings in *Science*, which proved to be crucially important.

For reasons which I will not list here, Myriad continued to file patent requests, eight in all. Their demands[1] were grouped together into three European patent requests which were granted in 2002.

The first patent concerned diagnostic methods ; the second was the BRCA1 gene altered by mutation and demonstrating a predisposition to breast cancer ; and the third was the normal BRCA1 gene, which served as a reference in detecting these mutations. One of the ultimate aims was to develop genetic therapy, but the three patents included demands relating to the diagnostic method.

[1] A patent includes a description of the invention followed by demands, in other words, a list of intended applications for which the person making the request (the patentee) asks for exclusivity.

This method was very simple : from a sample (normally a blood sample), one could determine the sequence of the BRCA1 gene in the patient which could then be compared with the reference gene. Hundreds of possible mutations were identified, about half of which were relevant, in other words, they were considered to be markers for the predisposition to breast cancer. If the patient's DNA had characteristic features, then the test was positive.

Obstacles

I was then contacted by Dr. Stoppa-Lyonnet from the Curie Institute who brought the following problem to my attention. Members of the same family that she was treating tested negative using the Myriad test, and yet, several women in this family had had cancer, which would suggest an increased likelihood of genetic predisposition. Dr. Stoppa-Lyonnet tested them using the so-called "DNA combing" method and noticed that their DNA did indeed show a transformation which had not been detected by the Myriad test.

The doctor was worried because several lawyers had advised her that if she continued to use the « DNA combing » method, she would be infringing the Myriad patent. I agreed that this was indeed true : the patent simply stated that by comparing the reference gene with that of the patient, the differences could constitute a marker for the susceptibility to breast cancer. Therefore, any use whatsoever of a method of comparison was an infringement of the patent !

This conclusion was unacceptable to her as well as to a number of her colleagues and they considered taking legal action to oppose the patent. They asked for my help.

Unacceptable demands

In the belief that a bad financial arrangement is always preferable to a good lawsuit, I acquired information about the conditions of the Myriad licence. Not only was Myriad asking for two thousand five hundred Euros for the first family test and forty Euros for subsequent tests, but the company was also demanding that the analyses be carried out in their laboratories in Salt Lake City. The reason was that if they carried out the test themselves, on the basis of a pre-defined scheme, this would guarantee that the results could be faithfully reproduced. This was contrary to practices in French cancer centres which do not have a uniform protocol.

Needless to say, this caused an uproar. Social Security could not meet such a high cost. The Ministry for Research feared that since such analyses could not be carried out in France, this would result in a major scientific loss to our laboratories, despite the fact that there were still mutations to detect and numerous statistical studies to pursue.

The heads of all the French cancer centres as well as various authorities met, and everyone agreed that they had to oppose this patent, and that their rationale would be based on the non-patentability of the human gene. I agreed to head up the operation, but not on this basis.

Patentability of the human gene

The case for the non-patentability of human genes had been put before the EPO more than twenty years previously and without success, and the recent European directive (98-44) concerning biotechnologies endorsed the patentability of the human gene with certain conditions.

What is no longer possible

The first registration of patents on DNA sequencing date back to 1991. I handled some of them myself. At that time, some patents related to sequencing or even a complete genome, and the report could easily be several thousand pages long. Since these requests had no specific industrial application, they were worthless and were never granted. For example,

recently the Icos decision was made concerning the V28 gene, presented by its inventors as a receptor gene, but without indicating its future use. The patent request was turned down.

The EPO example

The second generation of human gene patents registered is illustrated by the EPO (erythropoietin) case. This is a product which can be used to help cyclists cross mountain passes in the Pyrenees in the Tour de France, but is mainly used in dialysis patients. EPO is a naturally occurring hormone which can be produced by genetic engineering and because of this, its patent has been the subject of numerous legal opposition proceedings both in the United States and Europe, although it remains under patent.

Patents granted for bio-computing

The third generation of patents registered on the human gene is in the process of being developed : these are DNA sequences whose function is determined by bio-computing. The computers analyse DNA sequences throughout the night. They suggest hypotheses regarding possible uses in comparison to other sequences which already exist and which make codes for enzymes, receptor genes, and may help in certain diagnostic or therapeutic applications.

In the morning, one merely has to transfer the list of these sequences and their application hypotheses to pre-formatted patent requests, before signing them, and sending them to the EPO.

Many people are disturbed by use of such a method, but in patent law no mention whatsoever is made about the way in which the invention is 'supposed' to be discovered : the inventor may make his discovery while shaving one morning or after spending years working on it with fifty engineers.

This system was used for the patenting of the CCR5 gene, registered by the company Human Genome Science (HGS) in the form of what is called a 'laundry list' : for a gene whose precise function was not known, its inventors had listed three pages of possible applications, in the hope that among them there would be at least some applications which were usable. They were in luck, because two years later research workers discovered that this gene was the co-receptor of the Aids virus. And yet, the HGS patent predicted that this gene could be a viral receptor. The company immediately announced in a scientific journal that it was the owner of the co-receptor of the Aids virus and during the night, the company's shares rose by 22 %…

Even though such a method is within the law, it is obviously appalling because it deprives patent consultants of legitimate revenues, and, most importantly, it overloads patent registry offices with work and bars the way for any future uses.

The best approach

In the knowledge that Myriad patents for diagnostic methods tended to be financially viable, I thought it was clear that we stood no chance whatsoever if we attacked Myriad on the issue of non-patentability of the human gene.

It proved difficult to convince the rest of the team. Many members wanted to make this case a matter of principle. But it had nothing to do with principles, it was all about business. If Myriad had not put such a high price on its testing, it is likely that they would have relented in the end. In any case, this is what I advised them, since legal action is always unpredictable and long-drawn out, and in the meantime, there is an uncertainty which is itself prejudicial.

Contesting the patent

I was chosen to represent the French group which included the Curie Institute, the Gustave Roussy Institute and the Assistance Publique-Hôpitaux de Paris (AP-HP : Welfare Services-Association of Paris Hospitals), and supporting them, the national federation of cancer centres. A second group included Belgian and Dutch institutions. The Italians also wanted to participate but they were too late and their request was rejected. Finally, representatives from the Green party also wanted to participate but only in relation to the non-patentability of the human gene which did not have a great deal of impact on the decision.

The process of contesting a patent begins with filing a report attacking the patent on one or more of the five following criteria : lack of originality, lack of inventiveness, lack of industrial application, inadequate description, and finally, unjustified extension of the patent beyond its original description. In general, the patent is attacked on all of these aspects since once the report is handed in, no other arguments can be put forward.

The patentee (ie. the patent holder) writes a response to this report. Exchanges can then take place and a date is fixed for a hearing at the EPO headquarters in Munich, with an Opposition Division made up of three or four members. In our case, the committee was made up of four people ; three specialist examiners from the biotechnology field, and a lawyer in charge of dealing with any legal questions arising from the session.

Decisions are made during the court session at the end of the hearing. The hearing may last several days and there are even sessions lasting eight hours without a break, which can be very gruelling. At any moment, the opposition division can ask technical questions on a particular page of your report or stop you when you digress too much, saying that your arguments are inadmissible. As far as the patentee is concerned, he can take into account the criticisms and modify his demands in order to come to an agreement. In our case, Myriad filed fourteen different successive sets of demands. These had to be answered one by one, and each time we had to adapt our original arguments.

Decisions are taken on each of the criteria (originality, inventiveness, etc.), and a final decision is pronounced which may maintain the patent, revoke the patent or limit it. A written decision is made and you have four months to contest it.

The result

Myriad lost, partly for reasons due to its previous filings of patent requests.

In fact, only the fifth patent request filed in the US described the gene correctly and the European patent request could therefore only refer to that particular request. However, this fifth patent request had been preceded by the publication of the DNA sequence in question in *Science*. The result of this was a lack of inventiveness in the patent and it was therefore revoked. It was simple but irrefutable. The Myriad representatives tried to put forward the case that there was a mistake in the formula published in *Science*, a mistake which had been corrected in the amended fifth request. However, it was blatantly obvious that this was a mistake which anyone in the profession could have corrected. This final contention lasted thirty seconds and the patent was revoked definitively.

In the United States, the system is different with the inventor having a year's grace ; therefore the fact that there had been a publication in the meantime would have had no importance[2]. In Europe, it was a different matter and clearly Myriad were unaware of this.

[2] The decision to revoke the patent taken by the EPO Opposition Division, according to the European patent convention, involves the exploitation of the invention within member countries of the convention. The law regarding American patents grants a period of grace between the publication and the registration of the patent, and therefore the Myriad patent is valid within the United States.

In view of the way in which these events took place, it is quite surprising that some commentators interpreted this decision as a victory for the non-patentability of the human gene. If the Myriad patents had not been flawed as I have described, they would most surely have been maintained since the patentability of human genes with an industrial application is accepted today.

Economic impact

The real problem posed by the Myriad patents lay elsewhere, namely in the staggering cost which would have been incurred by French Social Security system in diagnosing this cancer if the patents had been granted.

The case of the BCRA1 gene is merely one of thousands. In a short space of time, the problem will exist for haemochromatosis the diagnosis of which affects two or three times more patients. It is also possible that there will be tests to assess the potential response to cancer treatments since some of these treatments have no effect on certain patients, but still have very strong side-effects, and it seems that this is also for genetic reasons. Finally, there is more talk about diagnostic chips. These are small devices (1 sq. cm.) and with one test on several hundred genes determines the type of cancer, and by the same test on several other hundreds of genes discovers the appropriate treatment.

These new advances obviously pose ethical problems principally because clearly insurance companies are very interested in knowing which people are likely to develop cancer or other diseases, and this will put medical confidentiality severely to the test.[3].

These advances also pose a problem regarding economic feasibility. For example, the Curie Institute envisaged carrying out diagnostic tests on sarcomas which are another type of cancer. These tests involved fourteen different genes of which five had patents. If one added up the royalties demanded by the various groups concerned, it already came to 12 % of the price of the test. By using the PCR (Cetus/Roche) method, which is also possible for this application, the percentage rose to 33 %. Undoubtedly, the manufacturer of a diagnostic chip applying to about one thousand genes could easily find himself infringing on the patents of several hundreds of them. The impact of this type of change will be enormous both in economic terms and in terms of public health.

Solutions

There are several solutions which might avoid this risk.

Calling into question the patentability of human genes

The first solution would consist of calling into question the patentability of the human gene, but this would presuppose that all the member countries of the European convention signed up to the directive 98-44 would agree to a new wording, which I think would be very unlikely.

Limiting the impact of patents

The second solution would consist of trying to limit the impact of patents. This is what France wanted to do when events surrounding the modification of the European directive 98-44 arose, by claiming to limit the impact of each patent on a gene with a specific application. This is however contrary to general principles of European law. The European directives aim to harmonise national laws so that companies are treated the same throughout the EU and do not have to renew the same procedures. However, if each country modifies them differently,

[3] In France, bioethical law forbids insurance companies from communicating data on indiviual's genomes and adjusting their premiums accordingly.

then the whole device loses all sense… France is a specialist *par excellence* in this sort of paradox : it is very European in theory but in practice keeps going on about the 'exception française'.

Regardless, I feel that the impact of this French modification is limited. Today, acquiring rights takes place on a European level ; solely exercising those rights depends on national law, and yet in the field of biology, most of the patents are European.

On the other hand, this restrictive change may have an impact on an economic level since this type of approach naturally worries investors. Why would they come to France and risk legal complications when they could easily carry out their activity elsewhere ?

Compulsory licences

When a drug is not produced in sufficient quantities or when it is manufactured under unusual conditions, the Ministry of Health may force the patentee to grant licences whose characteristics are defined by judges. When I suggested extending this possibility to medical devices and diagnostics, the rest of the medical team asked me if this procedure was sensible : *« – It has been in existence since 1968 and works very well. – But what is the legal situation ? – That's just it : it works so well that there is no need for jurisprudence ! »* In fact, every time a company has been threatened with a compulsory licence, it has given in. All that can be expected from a ruling is that it allows one to achieve the intended result even if one does not need it …

This extension of compulsory licences was accepted in mid 2004. If, unfortunately, Myriad was to appeal on the three decisions that it lost, and was to win its case, then the judges could grant a compulsory licence to the users of these patents (the French cancer centres), by fixing the conditions of these licences themselves. It is highly likely that they would be less costly than the royalties initially requested by Myriad.

Other countries have shown an interest in this procedure : Belgium has adopted it in this form and Canada is anticipating doing the same.

Creating patent pools

The solution envisaged by the creation of patent pools is contractual and it is often used in the electronics sector where it benefits from the fact that manufacturers have to agree on a common standard so that their devices can operate with other devices from other companies[4]. The owners of the different elements are forced to agree with each other, otherwise nothing can be manufactured. In the biotechnology field, there are no such standards. Furthermore, in electronics, discussions take place between important groups with relatively reasonable claims, whereas in biotechnology, there are often small companies which tend to think that their patents are phenomenally valuable and that those belonging to others are of no interest at all.

Conclusion

The first lesson that I draw from this experience is that we are wrong to feel inferior to the Americans. In this affair, we showed them that we were capable of facing up to them, and won, even when up against their toughest teams.

The second lesson is that generally speaking the EPO works as it should and has a jurisprudence which turns out to be reasonable.

[4] If communication equipment such as a fax machine were only able to communicate with the same-brand fax machines then the use and scope of a fax would be much reduced.

On the other hand, I am struck by the general lack of knowledge of patent rights and the economic implications, notably in the biotechnology sector. The Ministry of Research has only recently employed a specialist in patent rights and the majority of public bodies (and notably research institutes) are not adequately equipped in this field and do not even have fundamental knowledge in this area. It was only when Myriad announced the astronomic price of the test that my contacts discovered the link which existed between patents and the economy. Obviously, many people still have an outdated picture of patents and imagine that their aim is to reward an inventor for his efforts. This is not the case today : patent rights have become an essential economic weapon.

DISCUSSION

Research workers infringing on patents

Question : *What exactly did the Curie Institute want you to do when it contacted you ? In its capacity as a public research laboratory, it was exempt from paying royalties on patents. Did its request come from the fact that it hoped to profit from the development of tests revealing a predisposition to a particular disease ?*

Jacques Warcoin : The fact that public laboratories are in principle exempt could be called into question. When the CNRS (Centre National de la Recherche Scientifique : national centre for scientific research) accepts a research contract with a pharmaceutical company, are the tests it carries out classified as academic research ? Have we have not already changed in a direction which is more or less commercial ? Even outside this scenario, when a research worker suggests to his patient that he takes a test which can be carried out in a private medical laboratory, he is clearly infringing the patent if his institution does not have the relevant licence. The limit is difficult to define and this state of uncertainty is difficult for research workers to cope with. They find it very hard to work with this double-edged sword.
In the United States, things are much clearer. Pure research carried out for scientific curiosity or for philosophical purpose is said to be non-commercial. It is obvious that there are not many laboratories which work according to this principle. Apart from this, you are infringing patent rights : you do not even have the right to use a drug in order to compare it with yours despite the fact that the FDA (Food and Drug Administration) requires that you prove that your product brings an improvement to the market.

The only thing which reassures French public laboratories at the present time is that it is very unlikely that an American company would sue them in view of the poor likely financial return between damages incurred and the cost of a lawsuit.

The European directive

Q. : *The European directive 98-44 was adopted amid a certain amount of confusion. All the French political parties voted for it in the European Parliament, apart from the Green party and the National Front, but the same deputies applauded the Fiori Report which, in 2001, declared that no-one could appropriate the human gene. Finally, the French Euro MPs reversed their approval following the modification of the European directive.*

Q. : *Everyone knows that the European deputies were taken for a ride because of a paragraph which was added after the first presentation…*

J. W. : Despite it all, the consensus for which the European directive strives seems preferable to the existence of a multitude of laws throughout Europe. We have already been faced with very important differences betweeen the American and the European approach. If we introduced something even more complex, this would make lawyers and consultants even richer, but it would not necessarily be in the public interest. On the other hand, at the same time as acquiring a consensus, which is the aim of directive 98-44, one could envisage national strategies for people to use their rights such as compulsory licences.

Patenting a natural product

Q. : *Fundamentally it is still shocking that a natural product can be patented.*

J. W. : The question was already settled in the 1970s. It had been proposed for a patent on micro-organisms used for the manufacture of antibiotics. This patent had been attacked on the grounds of its originality since this micro-organism already existed in nature where it already carried out this function. The legal position was that, in nature, this micro-organism lived symbiotically with many others and that it was only from the moment when it had been isolated and identified that it was transformed industrially. It is exactly the same approach which was taken with genes.[5]

The economic model of diagnostic patents

Q. : *How did the price of Myriad's test come to two thousand five hundred Euros ?*

J. W. : The test itself is relatively costly : it must cost about eight hundred Euros. They probably decided to multiply this figure by three.

Q. : *I have been investing in capital risk for the past fifteen years and I have never invested any money on diagnostic methods for the simple reason that nobody is capable of determining the economic value of a test which determines whether the individual is predisposed to a disease. Even in the United States, there is not one major company in the diagnostic field. Myriad is a middle-sized company.*

J. W. : It is undoubtedly true that people are more willing to accept the principle of having exclusive rights lasting twenty years for a drug which took twelve years to develop than for a diagnostic method whose development is much simpler. Once the gene has been isolated, it is handed over to a company which manufactures the kits, and six months later, it can be put on the market. Two years ago, the OECD (Organisation for Economic Co-operation and Development) organised a meeting during which it was made quite clear that if one day the patent system was called into question, it would principally be because of this particular case of patents on diagnostic methods.

If Myriad succeeded in finding investors, it was because its final objective was not to develop diagnostic methods but genetic therapies. The diagnostic tests were merely regarded as a means to earn a small amount of money quickly in order to contribute to the self-financing of the development of genetic therapies… Unfortunately, genetic therapies have not lived up to their promise.

Q. : *However, if Myriad had not made these mistakes in its requests for patents, the Europeans would certainly have had to follow these conditions for twenty years. At the rate of two thousand five hundred Euros per test, this would have proved to have been extremely lucrative. In what way could this business model have been contested ?*

Q. : *The outcome of this affair shows that when one launches oneself into this type of operation, one has no idea what will be the final value of owning the rights to one's patents. Furthermore, the inventor of a diagnostic method may, as you suggest, find himself forced to pay royalties out of his own pocket to those holding other patents which reduces his profit margin.*

[5] Similarly, the fact that it has always been known that a brew of willow leaves in vinegar relieves a migraine has not prevented acetylsalicylic acid (otherwise known as aspirin) being patented. This patent was judged to be of such value that it was part of the compensation demanded from Germany after the First World War.

J. W. : It is obvious that if you manufacture a diagnostic chip containing one thousand genes, but you only own one of them, and you have to pay 3 % of your sales price to the other ninety-nine, your business will fold…

Q. : *All of these mechanisms create a huge uncertainty about the final result which is why the investors are not keen. The analysis which we make in my capital risk company is that regardless of the value of the technology, it will be the ones with the most money who will win, in other words those who are capable of mobilising fifty lawyers for this sort of case. In this context, investing in a technological leap makes no sense since technology takes second place behind the economic weight of rival companies.*

Obsolete technology ?

Q. : *The question of the economic value of diagnostic methods is even more pertinent since a technology such as Myriad's already appears to be obsolete. In fact, the progress accomplished in the biotechnology field is meteoric : it took Marie-Claire King three years to show, with help from the consortium, that the BRCA1 gene was responsible for certain breast cancers. One can predict that in five or six years' time, it will possible to determine in a matter of days and from an ordinary blood test, the map of the entire genome of an individual.*

Q. : *As a doctor, geneticist and member of the National Ethics Committee, I would like to add a detail : it is an illusion to think that one can automatically categorise all the predisposing factors of an individual. The environment has a considerable impact on the development of diseases, which in general are multifactorial.*

The advantage of diagnostic tests for assessing predisposition to disease

Q. : *The question of the economic value of diagnostic methods can be phrased in a different way : should one really try to diagnose our predisposition to disease ? Do we really want to know how many cancers we run the risk of developing ?*

J. W. : The question can of course be asked even for breast cancer about which I have been talking. It is true that one cannot offer preventative treatment for cancer unless one resorts to a radical methods such as those currently used in the United States : when a woman has been diagnosed as being susceptible to developing breast cancer, it is suggested that her breasts and ovaries are removed even before she develops the disease ! I asked the experts who replied that, on the one hand given a known predisposition to cancer, in 50 % of cases this procedure prevented the development of metastases ; on the other hand, the knowledge of such a predisposition could prevent false diagnosis.

For example, a case was made out for rare disorders of the central nervous system. A company had perfected a test which enabled the identification of the gene responsible for these types of disorders. However, in the absence of any possible treatment, Social Security had reservations about reimbursing patients : the sole point of the test seemed to be to tell the patient that in six months to a year, he might well find himself in a wheelchair. The doctors pointed out that this test enabled one to avoid having to resort to other tests which were equally costly, and also to avoid making false diagnoses which would result in patients being given treatment which was sometimes complex and potentially had serious side effects.

The teaching of patent rights

Q. : *If these questions concerning patent rights are so poorly known in France, it is because they are rarely taught in engineering schools or during postgraduate studies.*

Q. : *Rubbish ! I do not know of any engineering school or postgraduate school which does not offer a course on the importance of patent rights.*

J. W. : It is true that there are sometimes courses, but in general they focus on the academic aspects of patent rights. We explain what is patentable and what is not, what 'inventiveness' means, and so on. On the other hand, students are not necessarily aware of the strategic uses to which patents can be put, nor the huge economic impact of such strategies.

Q. : *We are in the process of proceeding from a civilisation concerned with tangible things to an information society, yet we have kept a patent system which was devised in the middle of the 19th century. The fact that we can now produce patents automatically by using computers reflects this change, but because we did not realise the impact which this produced, absurd anomalies ensued. It is a matter of urgency, not only to teach the rules of patent rights in schools, but also and most importantly to undertake research programmes to predict the possible changes in patent law on an international scale.*

Giving patent lawyers a sense of responsibility ?

Q. : *What is really scandalous about this system of patents, is the huge difference between the cost of registering a patent (ten thousand dollars in the United States) and the cost incurred in opposing it, if you were asked to do so. Even the costs incurred in examining the request in the first instance – if it was correctly carried out – are high. The EPO does quite a good job, but the American Patent Office has completely given up. In the United States, one can obtain a patent for practically any object and that is when the problems start. If one made patent lawyers similar to present-day auditors, would that not be a possible solution ? In the past, all you had to do was to give them a good meal and get them to sign. Nowadays, we have made them have a personal sense of responsibility for the accuracy of their accounts, and their methods have totally changed. If patent lawyers were obliged to write the patent request correctly it would greatly help the work of examiners who have to judge the inventiveness of requested patents.*

J. W. : The notion of patent lawyers being made to feel responsible is beginning to spread. For example, one of my colleagues was sued in a case involving brandnames. The judge thought that the preliminary research had not been done correctly. It was all to do with a perfume whose name was *Après l'amour* which proved to be an infringement on another perfume called *After Love*. Clearly the consultant should have done some research into potential translations and therefore had not done his homework. It is likely that in certain cases there will be a shift from being means-oriented towards being results-oriented.

Compulsory licences

Q. : *The Americans have always been very hostile to any compulsory licensing system. However, in October 2001, when the anthrax problem reared its head, they did not think twice about scorning Bayer patents to get hold of the vaccine quickly and in sufficient doses.*

J. W. : That's true, and since then, they have been a lot more discrete about patents…

Q. : *In view of both its public health and economy, South Africa has asked to be exempt from licenses for drugs to combat Aids. Can the major pharmaceutical companies hold out any longer in the face of pressure from populations which are not creditworthy ?*

Q. : *Since our compulsory licence system is in the process of being exported to different countries, South Africa could use this system and distribute tritherapies for a dollar each.*

J. W. : As far as I am aware, the important pharmaceutical groups have suggested giving free access to patented drugs to developing countries whose population earns less than a dollar a day. One of the difficulties is the exact definition of a developing country. Some countries are relatively rich, but include sections of the population who are very poor, as in the United States. Another difficulty in countries whose political systems are often in decline, is to prevent the re-exportation of these drugs at low prices to creditworthy countries. Of course, these pharmaceutical companies fundamentally do their best to make sure that the patent

system is not called into question itself, because this would jeopardise the entire pharmaceutical industry.

Presentation of the speaker :

Jacques Warcoin : partner in the Regimbeau patent law firm since 1983 ; he is in charge of cases relating to biotechnology and biochemistry ; he is a chemical engineering graduate from the École nationale supérieure de chimie de Toulouse (ENSCT) and an expert in industrial property ; he is a registered European patent and trademark lawyer at the EPO (European Patent Office) and the OHIM (Office for Harmonisation in the Internal Market) ; he is a member of numerous national and international organisations and is an expert in the Ministry of Research (Actions Concertées Incitatives ; Young Researchers) ; he has also written a considerable number of articles and has spoken at numerous conferences (OECD, UNESCO…).

Translation by Rachel Marlin (marlin@wanadoo.fr)