Protecting Biological Inventions – A Well-defined Issue?

Of the three major sciences, physics, chemistry and biology, the biological sciences are the baby of the family. As such, our understanding of biological systems is less well-developed than our understanding of the physical and chemical world around us.

The basic laws of physics, at least insofar as they relate to our world, were established hundreds of years ago and underpin our application of physics to our environment, particularly in engineering. Equally, our understanding of chemical principles allows us to have a clear understanding of the roots of advances in chemistry and chemical engineering.

Much of the technology in these fields can be described in a sort of technical shorthand, because the principles and laws on which such developments rest are implicit, not just to those working in the relevant fields but to anyone with a basic interest in science. Because of this, authors writing about advances in these sciences can refer to effects, confident that the reader will immediately grasp the cause of those effects.

This is much less true of technological advances involving biological systems, wherein the underlying principles are often still to be figured out. Of course, it makes biotechnology an exciting field in which to work, but it also raises a unique set of problems when trying to use patent law, to commercially protect those developments.

The relationship between science and the law is always a little fraught. Science is based on the understanding that nothing can be proved beyond doubt, only disproved. The law, on the other hand, requires certainty, no more so than in the use of language to define concepts and boundaries.

Our understanding of how living organisms work on a molecular level remains hazy. As the biosciences progress, the networks of complex interactions and feedback loops in organisms continue to reveal themselves as increasingly intricate on many levels. Our understanding of molecular interactions in biological systems continues to increase, but is not at the stage where we properly understand cause and effect.

The tension between the hazy understanding of the complexity of biochemical pathways and relationships, and the insistence of the law on clarity and certainty, leads to considerable difficulties when patenting biological inventions, because patent law requires clear definition of the invention being protected. In many cases, this difficulty in defining a biological invention arises because the molecular interactions underlying the invention are not well understood.

For example, the invention can reside in the discovery of a function of a compound, without a clear understanding or elucidation of the structural motifs of the molecule which give rise to those functions.

European patent law further heightens those tensions because not only does it require that the applicant for a patent clearly defines its invention in the original patent application, but it also does not allow the applicant to add anything to that application after filing. This rule is applied rigidly, even if the European Patent Office (EPO) discovers new evidence which may cause the applicant to want to amend the invention definition, because the evidence alters the perception of what part of the subject matter of the invention might be patentable.

On a practical level, the examiners in the EPO are very uncomfortable with such a disconnect between function and structure. They do not like to grant patents for biotechnological inventions, which define the invention solely by its function.

This reluctance of the law and some examiners to engage the realities of the science makes it difficult to get biotechnological patents which are of an appropriate breadth. For the applicant, it is especially important to ensure that the application contains as much subject matter as possible, to forestall potential objections to the way that the applicant has defined the invention. Because the EPO will not allow the applicant to add anything to the application after filing, the original application must contain information to enact not only plan B, but plans C, D and E as well.

The first issue facing applicants for biotechnological patents is that the EPO often confuses function with the result to be achieved.

An applicant cannot define an invention by the result to be achieved – in the profession this is known as a “free beer” claim. Take a scenario where an applicant discovers that compound W cures the common cold. A “free beer” claim defining the invention in their patent application would read “A compound which cures the common cold”. Unsurprisingly, the EPO will not allow this, because it covers all compounds which might work, most of which the applicant will have taken no part in discovering.

This much is logical. The problems really come where, as often happens, the applicant not only discovers the compound but discovers the manner in which it functions to treat a condition.

For example, the applicant may discover that compound X can cure osteoporosis, but also discovers that it does so by activating a receptor, Y. This discovery takes the scope of the applicant’s technical advance beyond a single compound, to encompass a whole group of compounds that can treat osteoporosis.

In such a case it seems logical that the claim defining the invention should read "A compound which activates receptor Y for treating osteoporosis", and, indeed, many applicants define their invention this way in their patent application. (In case you are wondering why a treatment should be defined this way, the EPO will not allow a patent where the invention is defined as a method of treatment, but will allow a patent to a compound "for use" in that method.)

Unfortunately, many examiners at the EPO are uneasy with such claims, couched in such purely functional terms. In particular, the examiners worry that the invention, defined this way, is not new (inventions must be new and inventive), is not clear (the definition must be clear so that third parties can easily decide if they might infringe the patent) and is too broad (the definition of the invention should reflect only its contribution to the field, and no more).

The examiners' novelty issue is driven by practical concerns. If the applicant defines the group of compounds solely by its function, EPO examiners worry that known compounds, already known for the same purpose, may inherently have that function but not be documented as doing so.

In the example I have chosen, an old drug, Z, may already exist for treating osteoporosis. The literature may not say that it activates receptor Y but, if it does, then it is a compound that treats osteoporosis and activates the receptor Y. If that were so, the defined invention would not be new, because it includes a known compound (Z) for a known use and so would not be patentable.

Although the EPO should give the applicant the benefit of the doubt, examiners often do not, at least not without some evidence to satisfy them that none of the compounds, previously known for treating that disease, inherently have the claimed function.

The second issue is the clarity of the definition. This is a very difficult one to avoid, unless you remain objective when initially deciding how to define the invention.

The EPO likes an applicant to use

structural or numerical definitions if possible. For example, examiners like compounds defined by a formula, or amino acid sequence, and like values defined numerically rather than by effect ("…in an amount sufficient to treat osteoporosis", for example). Any subjective definition will cause them concern.

Returning to our example of a group of compounds which activate receptor Y, the receptor will (or should!) be defined structurally, or by a name that is generally understood in the field. However, many EPO examiners will object to the term "activates". How do you know when the receptor is activated? What effect must you be able to see? What test do you use to determine if the receptor is activated? What results are you looking for to demonstrate "activation"?

The examiner will often argue that, in the absence of that information, the definition is unclear. Their position will be that a third party, developing a drug, may not be able to tell if it "activates receptor Y", because they don't have the answers to these questions, and so cannot tell if their compound falls within the definition i.e. infringes the claim.

Finally, there is the issue of the breadth of the definition. Many

examiners may have concerns that, of the wide number of compounds that might activate receptor Y, a large number cannot also treat osteoporosis. Sometimes they even have good reasons to support those concerns. In those circumstances, they will argue that the applicant is claiming more than they are entitled to, and will require that the claim is narrowed.

So how do you avoid these problems?

The answer is to prepare, and that involves shifting your focus away from the function of the invention (although that is likely to be the scientifically exciting part of the development) to the practical definition of *how* it achieves that function. You should also be prepared to accept that, if you cannot find underlying structural motifs aligned with that function, you may not be allowed to protect everything that works in that manner. You should always look to plan B – structurally defined groups which have the function.

To prepare for potential objections that previously known compounds had the relevant function, you should include in the application technical reasons why they did not. The one advantage that the applicants have at the EPO is that the balance of probability is with them – if they can provide evidence that known compounds did not have the relevant function, the examiner is likely to accept their position. If you can include appropriate technical reasoning to explain why compounds having the relevant function are new, that may forestall such an argument.

That does not mean to say that you should not have a fall-back position. If you rely solely on the function of the compound and a third party challenges your patent, and shows that just one known compound activates receptor Y (taking our example), this would invalidate the whole patent. However, if you can narrow the definition to exclude that known compound, you may be able to overcome the challenge.

Therefore, you should try and delineate groups of compounds which have the relevant function and, if possible, try and find structural motifs that the groups have in common. If our example related to proteins, and you found that a specific nine amino-acid sequence is required to activate the receptor, that sequence could be used as an additional, structural definition of the invention compounds. The EPO is much more willing to accept a definition involving a function, if it also includes a structure.

You also need to prepare for clarity objections. To do this, when you come to define the function on which the invention relies, you must consider what every word in that definition means. You should then devise further definitions of those terms, structurally and/or numerically, if possible. These may have to be a little narrower than your preferred wording – but the EPO is more likely to allow patents using those definitions.

If the function can only be defined by simple experiment, then you must decide upon (and include in the application) a clear and detailed assay or test for assessing whether or not any given example has that function. The application must also set out those values from that assay or test which indicate that the tested example has the function.

In our example, you will need to explain what test is to be used to determine if receptor Y is "activated", and what value in the test is the threshold, above which the receptor is deemed "activated".

Finally, to avoid arguments that the claim is over-broad, you should provide technical reasons (or, better still, wide-ranging data) to explain why everything having the defined function will work.

It is important to remember that those reasons must be in context. It is all very well arguing that phenol compounds can be used to activate receptor Y *in vitro*. If the claim is to the use of those compounds for treatment of osteoporosis, the EPO will object that such toxic compounds should not be given to a patient, irrespective of whether or not they might activate the receptor, and so you still have not shown the therapeutic effect across the whole definition.

Once again, you should also have a plan B, in case you cannot convince the EPO that all compounds will work. You should include in the patent application teachings of smaller groups of compounds, defined either by a function more closely related to the end result, or by structure.

Finally, it is absolutely vital, for every aspect of the definition of an invention, to have multiple sub-definitions to which you can retreat if necessary. It is also important to convince the examiner that your invention is truly effective, to have as much experimental evidence as possible. It is true of any aspect of science, even where it collides with the law, that data remains king.

Of course, your patent attorney will ask you for all this information when drafting your application. But if you start thinking about these aspects of the invention at that late stage, you run the risk of being underprepared. It is much better if you are aware of these issues through the entire development project, and devote at least some of the development work laterally to their consideration.

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