

IN EINSTEIN'S FOOTSTEPS

Dependent patents in biotechnology

Dr. Ralf D. Kirsch, Claus Becker and Dr. Thomas Westphal,
Patent Attorneys Glawe, Delfs, Moll, Hamburg, Germany

▶ Patents that cannot be used without violating the scope of another “ruling” patent are known as “dependent patents”. Comments made by Albert Einstein about “dependent patents” in a 1919 patent case are still valid today. Dependent patents in the biotech field are often based on a “selection invention”, where a selection of a narrow region having surprising effects is made within a broader, better-known region (e.g. certain dose ranges of a pharmaceutical formulation, enzymes, etc.). Selection inventions are usually patentable, and generally work particularly well as Europe-wide patents. Unfortunately, one exception to the rule is Germany, where national case law on selection inventions is more restrictive.

Many are surprised to discover that physicist Albert Einstein was initially employed as a patent examiner (“Technical Expert of the 3rd class”) at the Swiss Patent

Office, and even more surprised to learn that he was also a valued expert in patent infringement proceedings – for example in “Anschuetz & Co. vs. Kreiselbau-

Gesellschaft m.b.H), a case which was on the infringement of a patent granted in 1917 for an airplane part.

Einstein’s expert opinion on this has been published¹, and is of particular interest with regards to selection inventions in the area of biotech or pharmaceutical patents.

What is remarkable is that after Einstein had commented on the questions raised in the infringement proceedings, he explained his model in his expert opinion commentary on a “dependent invention”.

Dependent patents are hard to exploit – cross-licensing as solution

The dilemma of an inventor who owns a “dependent invention” is that he cannot profit from it (whether patented or not), because the dependent invention falls into the scope of the ruling patent, and the owner of that ruling patent has a prohibitive right that is granted by the patent. This is in line with one of the fundamental rules of patent law: to exclude others from using the invention.

Thus, it is not surprising that disputes like those described in the infringement proceedings above, as well as ones that occur during licensing negotiations, are not uncommon. Here, the owner of the dependent invention is dependent on the goodwill of the owner of the ruling patent, which is usually gained through reimbursement processes such as the payment of licensing fees.

The owner of the dependent patent (e.g. of a “selection invention”) can strengthen his position vis-à-vis the owner of the ruling patent by filing his own patent application for a dependent invention himself. This could then be used effectively in negotiations. Even so, the owner of the ruling patent would probably continue to retain a prohibitive right for the dependent patent. That means that without the approval of the ruling patent’s owner, it remains impossible for the owner of the dependent patent to “work” the invention. The way out of this dilemma is usually accomplished by exchanging licences (“cross-licensing”), where both parties

“... To each invention described in a patent belongs a certain region G of options on how to realize the patented invention. Let us think of said region G as a certain, limited area of a plane of all possibilities ... Subject-matter that is part of the invention can be thought of as a point (black circle) within said region G.”

Would the inventor of the patent that is protecting the region G have complete knowledge of all the possible embodiments of the invention, he would indeed be without any doubt the intellectual owner of all possible embodiments of his invention. In real life, however, the inventor never has a complete overview of all the possible embodiments of his invention. In a way, he does not know about all of the points in his region G, but only about a certain limited number of points of this region. However, there can be embodiments of the invention of which the inventor himself had not thought of, and which bring about novel, characteristic technical advantages (the finding of valuable points P or subregions of the region G, which had not previously been seen). In such a case, one can speak of a “dependent invention”. The question of whether to assign an inventor of a “dependent invention” any rights is not to be discussed by myself; this is up to the attorneys ...”².

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agree to allow the other to commercially use the respective invention in exchange for a licence fee. If licensing negotiations are unsuccessful, the dependent patent (e.g. on a "selection invention") can often only be commercially exploited after the ruling patent has lapsed – often far too long to wait for a return on the investment. The additional possibility of a "compulsory license" on a ruling patent will not be discussed here.

The importance of selection inventions in biotech

What is interesting about this field is that "selection inventions" are particularly important in the biotech and pharmaceutical areas. As an example, let us assume that a ruling patent from company A protects an organic or biological compound X for the treatment of disease Y. The upper limit of the daily dose is given in the patent as 20 mg, and the examples in the patent disclose daily doses of 15, 18 and 20 mg. However, the R & D of a competitor, company B, has discovered to their surprise that compound X is at least 100 times more effective when it is administered to the patient in a daily dose of only 1-3 mg (the molecular mechanism that could provide the basis for this example is immaterial).

First of all, this sub-region of 1-3 mg is narrow in comparison to the known, patented region (up to 20 mg). Second, it is distant from the examples of the known, patented region (15, 18 and 20 mg), and third: it is not a randomly chosen sub-region – instead it is a purposive selection of a region, since it could be shown that the

surprisingly high effectiveness can only be observed in the particular sub-region of 1-3 mg (as opposed to an arbitrary selection). Such a "selection invention" is patentable in Europe. The verdict is laid down in one of the hallmark decisions of the Technical Boards of Appeal of the EPO³. The three criteria for a selection invention listed above have been the basis for recent EPO decisions. It isn't difficult to envision many variations on the example described when it comes to selection of other doses (units of enzyme, doses of particular factors, or other parameters).

What this means in concrete terms for a biotech or pharmaceutical company is that a lot of findings that come to light in the course of R&D may be patentable in Europe, even if they fall into a broader range of a pre-existing "ruling" patent.

No patents for selection inventions in Germany

Although the option of a selection invention is open for European patents, there is a problem: the German part of this kind of European patent is unlikely to last very long there, since German case law has not accepted the principle of a "selection invention". In other words, the German part of the patent is open to attack by a nullity suit in Germany. German courts have taken the view that in the example above, 1-3 mg is comprised in "up to 20 mg", and therefore *a priori* an invention within that sub-region cannot be novel. Other countries in Europe on the other hand, including the UK, do have a practice of granting patents for selection inventions that is similar to the EPO practice.

One can only hope that German case law will eventually draw closer to the EPO practice of granting patents for selection inventions. Inventors all over the world who have made tremendous efforts in R & D deserve it.

About the authors

Dr. Thomas Westphal and **Dr. Ralf D. Kirsch** are both patent attorneys and partner in the IP law firm Glawe · Delfs · Moll in Germany (Hamburg, Munich, www.glawe.de

de). **Claus Becker** is a patent attorney candidate at Glawe · Delfs · Moll.



Dr. Ralf Kirsch studied biology and went into research in molecular biology, immunology and biochemistry at the University of Cambridge (UK) and at the Max-Delbrueck-Centre for Molecular Medicine in Berlin (Germany).



Dr. Thomas Westphal studied biology and spent years in research in genetics, molecular biology and biochemistry at the Lomonosov University in Moscow (Russia) and at the Martin Luther University in Halle (Germany).



Claus Becker studied aerospace engineering at the University of Stuttgart (Germany) and is entrusted with patent matters in the field of medical engineering.

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Contact

GLAWE DELFS MOLL
Patent Attorneys and Attorney at Law
Rothenbaumchaussee 58, 20148 Hamburg
Tel./Fax: +49-(0)40-4142910/-41429166
mail@glawe.de