The birth of biotech

2018 is an important year in the biotechnology calendar, marking anniversaries of ground-breaking areas of research. It also provides an opportunity to review related areas of patent law.

On the 25th July, Louise Brown, the world’s first ‘Test Tube Baby’, will celebrate her 40th Birthday. 1978 also marked the first time a patent application for a human gene was filed in the US, when the University of California filed an application directed to the gene for a human growth hormone. Since 1978, the field of biotechnology has progressed rapidly, and in doing so, presents new challenges to the European Patent Office regarding the patentability of biotechnological subject matter.

In its simplest form biotechnology is the exploitation and manipulation of organisms and genetic material for the development of useful technologies and products. Its origins can be traced back to the late 18th Century, where it was preceded by the field of zymology. This area was dedicated to the study of the biochemical process of fermentation and its industrial application in brewing beer and large-scale production of fermented products. The first UK patent for a biotechnological process (Patent No. GB 178701625) was granted in 1787 for a yeast like composition for use in baking.

Fast forward to the 1970s and the word biotechnology had very different connotations thanks to the discovery of the double helical structure of DNA in 1953 and the advent of recombinant DNA technology 20 years later. The 1970s saw a surge in research and development of biotechnological inventions, particularly in the gene technology area (see box 1 for a summary of the most important events).

This rapid increase in biotechnological-related inventions presented new challenges for the law in Europe relating to patents. The European Patent Convention itself was newly devised, with the first patent applications filed under the EPC on 1st June 1978. It became clear that legal provisions would be needed to address the interpretation and ethical considerations relating to the granting of patents for biological inventions/living matter.

The result was the Biotechnology Directive (Directive 98/44/EC of the European Parliament and of the Council of 6th July 1998 on the legal protection of biotechnological inventions) which turns 20 this year. Originally proposed in 1988, it was eventually accepted in 1998 following 10 years of ethical debate regarding the patentability of living matter. The Biotechnology Directive includes provisions specifying what is excluded from patentability for reasons of morality, which include methods of cloning human beings, and the use of human embryos for commercial and industrial purposes. The Directive also specifies that inventions based on an element isolated from the human body, or otherwise produced by means of a technical process, including gene sequences or partial gene sequences, are not excluded from patentability per se, however, an indication of function is required.

Since inception of the Biotechnology Directive in 1998, researchers in the life sciences have developed a multitude of analytical tools and can now generate a wealth of information and data about living systems. This has provided unprecedented insights into previously mysterious biological processes. The human genome project took 15 years and cost $3-billion to complete, whereas whole genome sequencing today costs as little as $1000 and can occur in less than 24 hours. Equally as important are CRISPR systems, which could allow direct editing of the human genome.

Genetic testing and personalised medicine is also seeing a new player enter the field. This area is bioinformatics and it blurs the lines between biotechnology and computer science. Companies are now developing computer tests and apps that are marketed and sold as solutions for medical applications. Companies such as 23andMe are already marketing inheritability tests that some fear could pave the way for ‘designer babies’ and the Sci-Fi themes of GATACA becoming a reality.

Bioinformatics combines various computational, statistical and mathematical tools to analyse and interpret biological data. It has been
particularly important in the analysis and generation of ‘Big Data’ that has come out of large scale sequencing projects. Such techniques involve the use of computer programs for comparing sets of DNA sequences to allow predictions to be made about structure and function. These predictions can then be used to develop experiments in the lab.

Such emerging and rapidly developing technologies again present challenges to the legal bodies responsible for examining patent applications directed to innovations within these areas. Existing legal provisions need to be interpreted and applied to technologies that had not been envisaged when the law was drafted.

There is little EPO case law regarding the patentability of inventions within the area of bioinformatics and what is available seems to be contradictory depending on who sits on the Boards of Appeal. In EPO decision T784/06 the Board of Appeal, made up of members from the biological division, found the patent in question to lack inventive step. The patent related to a genotyping test (step A) that used mathematical and statistical analysis steps via a computer program (steps B to E) to obtain a meaningful result. The initial step A was deemed to be the technical feature of the invention, whilst steps B to E were viewed as non-technical. The board considered whether these steps, when combined with the technical step can produce a tangible technical output. They made the decision that the patent lacked inventive step as the skilled person was unable to derive the information required to understand steps B to E. Their final decision was thus reached by ignoring the non-technical steps in the assessment of inventive step.

However, in the EPO decision T2050/07, the Board of Appeal was formed of computer scientists and they found the opposite to the previous case. They concluded that the non-technical features were distinguishable from the prior art and that the technical effect obtained required these non-technical features. Unlike T784/06, they were then able to use the non-technical steps in their assessment of inventive step.

It could be argued that had the case of T784/06 been subject to the same board as T2050/07, the outcome could have been different. However, the non-technical features of T2050/07 were disclosed in much more detail than those of the previous case and were allowed to be considered.

Recently, the EPO acknowledged that novel mathematical steps presented as part of a bioinformatic method can be considered to make a technical contribution and will be taken into account when assessing patentability in a similar way to software patents.

These cases highlight the need for a cross disciplinary approach when drafting these types of applications. The subject matter should be presented in a way that can be understood by an Examiner whose principle technical background and legal knowledge may lie in a different field to that of aspects of the technology set out in the application. Such clear drafting will aid understanding of the invention and appreciation of the contribution it makes to the field. The non-technical steps should be fully described and explained in light of their relevance to the biological problem they are claiming to solve.

The growth in biotechnology has become a major source of innovation and has contributed significantly to global economic growth. This has been recognised by the UK Government’s Life Science Industrial review and their commitment to underwrite EU research funding following Brexit, as well as increasing R&D spending to 2.6% GDP from the current 1.7% (for more information regarding funding in the UK Life Sciences sector, see Kate McNamara’s article (page 16) in the Autumn/Winter 2017 edition of Inside IP).

IP protection is an important factor in enabling growth and development of biotech companies, from small start-ups, to large pharmaceuticals. Biotechnology companies often invest around 40% of their budget in R&D, which in turn drives the cogs of the patenting system: figures from the EPO indicate the importance of biotechnology to the European economy, with patents granted covering a variety of fields ranging from medical and pharmaceuticals (55%), to industrial process (41%) and agriculture (4%).

It is therefore paramount to have a stable and coherent patenting system in place for biotechnological inventions that is able to adapt to the rapid advances in this area. Further, with life sciences becoming even more interdisciplinary, new challenges will be faced by the EPO as the law strives to keep up with the research.

Louise Brown’s birth was hailed a miracle and was one of a number of landmark achievements in life sciences research in the last 40 years. Who knows what the next 40 years will hold for biotechnological research.

Box 1: Key biotechnological advancement of the 1970’s, 80’s and 90’s.
1973: Recombinant DNA discovered
1977: The world’s first test tube baby was conceived in vitro
1978: First patent filed in the US for a human gene
1980: US patent for production of recombinant insulin
1987: First patents for PCR were approved in the US
1988: The EPO granted their 100,000th patent
1997: Dolly the sheep was cloned
1998: The biotechnology directive was finally approved

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