

Partner, **Sarah Lau**, trainee patent attorney, **Alberto Carella**, and associate, **Duncan Bull**, biotechnology specialists at European and UK patent and trade mark attorneys, Kilburn & Strode, outline what can be protected around IVF and reflect on important IP considerations that can help maximize protection in Europe and the US



Patent protection in fertility innovation

Around 15% of reproductive-aged couples worldwide are affected by infertility. Assisted Reproductive Technologies (ARTs) such as in vitro fertilisation (IVF), provide a lifeline to these couples, significantly increasing the likelihood of pregnancy. Technology around IVF is constantly developing, as researchers and doctors strive towards improvements in pregnancy success rates, cost-effectiveness and safety. Protecting inventions in this field is crucial. Patents and other intellectual property (IP) rights provide a key tool for this.

IVF remains a difficult subject matter for patent protection. Granting exclusivity to the rights holder to commercialize a particular invention, incentivises innovation. However, the rights granted to a patentee must be carefully considered against the rights of the end user for IVF, accounting for the ethical principles and financial accessibility to what many consider a fundamental human right. The result is a multitude of technologies surrounding IVF, many of which have been granted patent protection, and which are often subject to a high level of scrutiny.

What IVF-related inventions are being patented?

IVF technologies are well-established, but not perfect. Cheaper, more space-efficient IVF apparatus is in demand to help extend the opportunity of receiving IVF treatment in less developed nations. This is reflected in patent applications for IVF incubators and culturing vessels, even extending to IVF home-kits.

Another category of inventions lies in the numerous chemical compositions

used in IVF. IVF is a complex process, requiring different culture media and countless components with various functions, such as small-molecule chemicals, proteins and hormones. This complexity opens the opportunity to develop compositions which improve a variety of IVF properties, such as gamete viability, fertilization rate and survival of embryos after fertilisation. Examples of compositions appearing in patent applications include media containing antiviral agents to prevent infection of gametes or embryos, and media containing hormones and various micronutrients geared towards improving fertilization success rate.

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Methods for screening and selecting for healthy embryos/gametes and predicting IVF outcome are increasingly prevalent in IVF-related patents, reflecting advances in the understanding of embryo growth and development. These methods commonly involve measuring the presence or levels of certain markers, such as free metabolites, cell-surface lipids, proteins or nucleic acids from cultured embryos to predict the proba-

bility of implantation success. Surprising links have also been established, such as between the presence/proportions of certain microbial species in female subjects, and the likelihood of successful pregnancy from IVF.

Artificial Intelligence (AI) has emerged as a groundbreaking tool in many scientific fields, and this is no different for IVF. AI related IVF inventions seen in patent applications include using machine learning to predict embryo health and implantability by analysing images of embryos.

IP hurdles to patenting IVF-related inventions

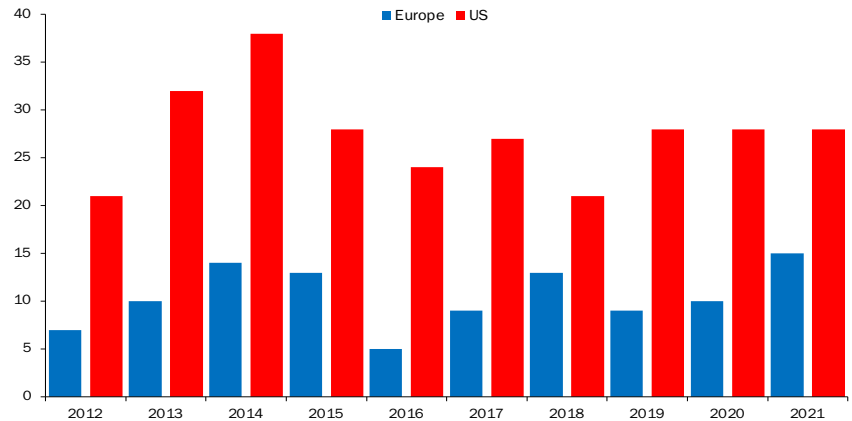
A patentable invention must satisfy two main criteria. Firstly, it must be novel (new), meaning that it has not been disclosed to the public in any way beforehand. Secondly, it must have an 'inventive step', meaning the invention was not obvious to someone who is skilled in the technical field of the invention.

Provided they are novel and inventive, applications relating to all the examples of IVF-related inventions above, are in principle eligible for patent protection at the European Patent Office (EPO) and the US Patent Office (USPTO).

However, there are a number of exclusions to patentability in Europe, the US and elsewhere which must be navigated when considering patent protection for IVF-related inventions. Both the EPO and USPTO consider that uses of human embryos should not be commercialised and that doing so would be considered immoral. Human embryos per se therefore cannot be patented as products of IVF treatment.

That being said, processes or methods to generate products of IVF may be patentable and careful consideration of strategies here can be crucial to maximiz-

**PATENT PUBLICATIONS WITH 'IN VITRO FERTILISATION' OR 'IN VITRO FERTILIZATION' OR 'IVF' IN THE TITLE OR ABSTRACT
2012-2021**



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ing commercially-relevant protection.

Additionally, methods that are practiced on the human body (e.g. surgeries and therapies) are typically excluded from patentability in Europe. A patent to a method of IVF including a step of actively implanting an embryo in a subject would therefore be ineligible for protection in Europe. However, compositions or medicaments for use in methods of treatment are permissible. Again, careful holistic consideration of the overall invention and advice from your European IP advisor will be needed to pursue robust protection of IVF-related methods in Europe.

The US differs with regard to subject-matter eligibility, allowing method of treatment claims practiced on the human body. Careful drafting of patent applications to help manoeuvre between these different jurisdictional requirements is a crucial starting point for ensuring the best possible protection.

Patent trends in the IVF space

Given the contentious nature of these inventions, there can be fluctuations in the patent eligibility rules following changes in public perception, or legal restrictions in other areas. A moderate increase in European and US IVF-related patent publications in 2013 and 2014 appears to have coincided with the grant of a controversial patent for imaging embryos during IVF. This case drew significant media coverage at the time and helped demonstrate that, despite differences in public opinion, the patent framework still allows innovators to seek protection for their inventions in this field. Over the past five to six years, IVF-related patent publications appear to have stabilised and continue at a steady rate.

IVG – the future of fertility?

Looking to the future, the next surge in patent activity within the fertility space may be sparked by advances in new ART technologies. A promising technology gaining far-reaching interest

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is in vitro gametogenesis (IVG).

IVG is an experimental technique which allows scientists to reprogram adult somatic cells into sperm and egg cells to be combined into an embryo in vitro. The prospect of IVG in fertility treatment is a game changer as it could obviate the need for potentially harmful rounds of hormone treatment given to women before IVF, eliminate the need for egg and sperm donors, and enable same-sex couples to have a biological family.

IVG proof-of-concept has been shown

in mice, and the framework of human IVG is now established. Briefly sidestepping the ethical quandary surrounding IVG in fertility treatment, it looks like this technology could be ready for human use within a couple of decades. While this may seem a distant prospect, the first patent applications for IVG are beginning to surface, with an upsurge predicted over the coming years.

Patent applications for IVG have similar patentability considerations as IVF. For example, human embryos per se produced from an IVG process are not patentable in Europe or the US. With the added complexity introduced by the prospect of product claims directed to stem cells for IVG, and the gametes produced from them, the considerations around patent eligibility are unclear. For example, some IVG patents may be turned down by the EPO if they are considered immoral, or contrary to 'public order'. Time will reveal the tolerances of both the patent offices and the general public for these sorts of claims to a legal monopoly on such technologies. Despite some uncertainty, many options remain for filing patent applications for IVG-related inventions, enabling strong protection for those developing IVG for commercial markets.

Clearly, the patent landscape for IVF-related inventions is vast, and is evolving in line with technology advancements in this field. As long as there is a need for improvements in IVF, and as new ART technologies come to light, patents will form a crucial role in their protection and commercialisation.