Alain Pottage

Dignity again

Article (Accepted version) (Refereed)

Original citation:
Pottage, Alain (2017) *Dignity again.* Reproductive Biomedicine Online. ISSN 1472-6483

DOI: 10.1016/j.rbmo.2017.11.008

Accepted Manuscript

Title: Dignity again

Author: Alain Pottage

PII: S1472-6483(17)30626-0
DOI: https://doi.org/10.1016/j.rbmo.2017.11.008
Reference: RBMO 1857

To appear in: *Reproductive BioMedicine Online*

Received date: 15-11-2016
Revised date: 23-11-2017
Accepted date: 23-11-2017

Please cite this article as: Alain Pottage, Dignity again, *Reproductive BioMedicine Online* (2017), https://doi.org/10.1016/j.rbmo.2017.11.008.

Short title: Dignity again

Dignity again

Alain Pottage

Department of Law, London School of Economics, London, UK

Corresponding author: Alain Pottage, Department of Law, London School of Economics, London, UK. E-mail address: r.a.pottage@lse.ac.uk

Comment [MD1]: Author department correct? Please provide full postal code, telephone and fax numbers

KEYWORDS: patents, time-lapse embryo monitoring

Abstract

Two recent contributions to this journal discuss a challenge to Stanford's time-lapse embryo monitoring patent, currently before the European Patent Office (EPO). Sterckx, Cockbain and Pennings (2017) would like to keep the morphokinetics of embryo division in the public domain; they argue that time-lapse monitoring (TLM) is a diagnostic method in the sense of European patent law and therefore unpatentable. In response, Pearce (2017) suggests that the jurisprudence of the EPO unambiguously says that TLM is not a diagnostic method. This commentary proposes an alternative legal ground for challenging patents relating to the principle of TLM, a ground that could be invoked before national courts and, ultimately, the Court of Justice of the European Union: TLM is not a diagnostic procedure but a process of selection that breaches the criterion of dignity in European patent law.

Lawyers and economists have long argued that patents serve the public interest by incentivizing innovation and promoting investment in technological development (for a sceptical analysis of this theory see Mirowski [2011]). Recent contributions to this journal consider whether time-lapse embryo monitoring patents are justifiable in these terms. An earlier exchange highlighted the foundational question of patent law: what quality of technical intervention is required to turn a natural phenomenon into a patentable invention? Is the duration of a cell cycle 'an indisputable and well-known

fact of nature' (Cohen 2013, p. 109), or does patent protection enable the basic science of TLM to be 'translated' into an invention with clinical applications (Reijo Pera 2013, p. 114)? In the European context, the question whether TLM patents respect the proper mission of patents is framed in terms of the exclusion of 'diagnostic procedures' from patentability. The opposition before the European Patent Office (EPO) argues that Stanford's patent encompasses a diagnostic procedure practised on the human body, and that it should therefore remain in the public domain. Before proposing an alternative ground of opposition, one should notice that the ability of any particular purveyor of TLM to secure market dominance, and hence to curtail the benefits of competition, might have less to do with patent protection than with the adroit exploitation of trademarks and branding strategies.

Of all the procedures used in fertility clinics, TLM is the only one that is proposed to patients under the ensign of a brand name. Practitioners have their go-to brands of, say, culture media, mineral oil, or embryo transfer catheter, all duly acknowledged in the writing up of research findings, but these brand names are not advertised to patients. So, it is striking to notice just how prominently the trademarks *Eeva* or *Embryoscope* feature on the websites of leading fertility clinics, set in texts that encourage the belief that TLM improves success rates. The website of one UK fertility clinic suggests — inaccurately — that the first baby to be born from a cycle involving *Eeva* was 'named after the test that gave her life' (GRCM, 2017; on the point of inaccuracy, see BBC Scotland [2013]). The market presentation of *Eeva* technology encourages patients to make the imaginary leap forward to the 'best' embryo, to the baby-to-be that will feature in the home movie version of the embryological time-lapse record. This 'puffery', to use the old legal term, goes on despite the fact that there is no conclusive evidence that TLM produces the benefit that really matters to patients; namely, enhanced pregnancy rates (Kieslinger *et al*., 2016). If TLM does produce a 20% improvement in implantation rates (Meseguer *et al*., 2013), it is still unclear to what extent this might be attributable to incubation conditions rather than the applied science of morphokinetics. A recent commentary drew attention to the 'hype' surrounding the technology, and to the methodological limitations of the studies on which claims about the effectiveness of TLM are based (Armstrong *et al*., 2015). Four fertility specialists responded with the observation that it was the duty of embryologists and physicians to 'stand back and inform patients on

the real benefit from any medical innovation', in this case TLM (Basile *et al.*, 2015). One of the co-authors was a practitioner whose clinic actively promotes the virtues of *Embryoscope* and whose research papers have done much to generate the impression that TLM techniques do improve success rates. This says much about the complicity between marketing imperatives and clinical science in the promotion of TLM. We know that fertility clinics are in the business of hope, and TLM is a particularly striking example of how hope is leveraged in a clinical context, technically and economically.

Nonetheless, the question of patentability remains crucial, and this commentary proposes an alternative basis for opposing the patenting of TLM in Europe. Instead of characterising the differentiation of 'good-quality' embryos from 'poor-quality' embryos as a diagnostic procedure, why not see it as a process of selection that breaches the patent law criterion of dignity? In *Brüstle* v *Greenpeace* (2011), the Court of Justice of the European Union (CJEU) held that inventions that 'used' human embryos for 'industrial or commercial purposes' were not patentable in the European Union. The decision was based on the premise that European patent law excluded patentability 'where respect for human dignity could be affected' (paragraph 34). The court held that 'any human ovum must, as soon as fertilised, be regarded as a 'human embryo' …since that fertilisation is such as to commence the process of development of a human being'. So, although they are only 'potential' human beings, embryos are imbued with full human dignity. It inevitably follows that the destruction of an embryo breaches the principle of dignity. The stem cell patent in *Brüstle* did not actually prescribe the destruction of embryos, but the CJEU held that one had to look beyond the 'technical teaching' of the patent to what was necessary for the working of the invention. And, although stem cells might 'live again', as part of the colony that manufactures tissues of interest, the embryo from which they were derived would necessarily have been 'destroyed'.

This might be a reason for suggesting that TLM patents contravene the patent law criterion of dignity. Although Stanford's patent does not 'teach' a process of destruction, embryo selection implies the destruction of 'poor-quality' embryos. Statistics compiled by the UK's Human Fertilisation and Embryology Authority reveal that of the 3.5 million embryos created in UK fertility clinics between 1991 and

2012, 1.7 million were destroyed, presumably because they were not considered suitable for transfer or cryopreservation, or because of patient preference (for the statistics see *Hansard*, 2013). If used within an elective single-embryo transfer protocol, TLM might not immediately lead to destruction. The process of selection would merely indicate the order in which embryos should be implanted in a succession of one fresh and potentially multiple frozen transfers. Although most of the embryos that undergo a process of selection will be destroyed, proponents of TLM patents might say that this statistical fact does not mean that embryo selection 'necessitates' — in the sense of *Brüstle* — the destruction of embryos. For example, prospective parents could, if they wished, decide to maintain their 'spare' embryos in a state of permanent cryogenic suspension. Or state regulatory bodies could intervene to mandate the same result. So perhaps the fate of spare embryos is, from the perspective of patent law, an externality.

But the patent law principle of dignity is breached even before the ultimate decision is made, in and by the very process of, selection. Time-lapse evaluation compromises dignity because the embryos in a cohort are treated not as ends in themselves but as a means to the selection of the 'best' candidate for transfer. The 'value' of each embryo is not inherent, fixed by and from the moment of fertilization; it is contingent on the outcome of evaluation and selection. The embryonic person's nature and destiny – its 'life chances', so to speak – are dependent on how it measures up to the other members of cohort and to the software-generated 'reference embryo'. In Europe, there are obvious historical reasons why procedures for the selection of the fittest are thought to involve a fundamental disregard for human dignity. According to EPO jurisprudence, 'morality' is the 'totality of the accepted norms which are deeply rooted in …European society and civilisation' (EPO 1995). Although few Europeans have read Kant's *Critique of Practical Reason*, the notion that persons are ends in themselves has been effectively 'translated' from the philosophical treatise into the basic ethical intuitions of Europeans. Interestingly, Sperling (2013, pp 152–168) suggests that Kantian principles are ingrained in German folk knowledge). And, by holding that human embryos have dignity from the moment of fertilization, the decision in *Brüstle* wrote this particular sense of dignity into European patent law. It gave legal form to the intuition that there is a decisive ethical difference between the 'grown' and the 'made' (Habermas, 2003), or between treating persons as though they

were unique by nature and treating them as though their worth depended upon their fitness for some socially or technically defined purpose.

In its initial ruling on the challenge to Stanford's patent the European Patent Office followed the reasoning in *Brüstle* to the extent of holding that an embryo is a 'human body', but it did not follow *Brüstle* through to its logical conclusion. In asking whether TLM qualified as a diagnostic method it individualized the embryo by asking whether 'it' was the subject of certain diagnostic steps. It thereby overlooked the fact that evaluation is an inherently comparative process, which begins with a cohort of embryos and measures the respective 'quality' or 'viability' of each by reference to an ideal model of morphokinetic stages (which is itself based on archived evaluations of thousands of embryos). So, even if one ignores the fact that it results in the destruction of most embryos, TLM breaches *Brüstle's* criterion of dignity because it purports to select the fittest 'human body'. Indeed, from this perspective, TLM cannot be a diagnostic procedure, precisely because it addresses a cohort rather than an individual. And the principle of selecting within a cohort is actually invoked in support of the argument that TLM patents do not privatise a natural phenomenon: 'there is no need to distinguish quality among as many as 5–10 embryos (or even more) in natural conception, and in nature women simply do not conceive outside of the body' (Reijo Pera 2013, p. 113). In other words, comparative selection is essential to the 'invention'.

This analysis might seem artificial to anyone familiar with the clinical and emotional complexities of the embryo selection process, but the Court in *Brüstle* emphasized that its definition of dignity was confined to patent law. Noting that 'the definition of human embryo is a very sensitive social issue in many Member States', the judges observed that the case did not require them 'to broach questions of a medical or ethical nature' (see *Brüstle*, paragraph 40). In particular, the Court emphasized that the object was 'not to regulate the use of human embryos in the context of scientific research' (paragraph 40*)*. So even if TLM were to be deemed unpatentable on this basis, clinics would remain entirely free to use TLM, and to market it to patients as vigorously as they do now. Patent law invokes ethical principles such as 'dignity' or 'morality' only to determine whether a technology can be patented, not whether it is ethical actually to implement and practise that technology.

It should be noted, however, that *Brüstle* develops an expansive conception of dignity. Although there were pragmatic reasons for holding that embryos were human from the first moment of fertilization (see paragraphs 26–28), the Court reasoned that the term 'human embryo' had to be understood 'in a wide sense' so as to 'exclude any possibility of patentability where respect for human dignity could be affected' (paragraph 34). So, the embryo is not just a potential human being; it possesses full human dignity from the moment of fertilization and should be treated accordingly. The Court emphasized that 'all processes which offend against human dignity are excluded from patentability' (*Brüstle*, paragraph 33). Destruction is self-evidently an offence against dignity, but if the embryo is as much entitled to be treated as an end in itself as any other human being, then any patented process that treats it as a means necessarily offends against dignity.

Although I focus here on its application to time-lapse microscopy patents, one should pause to notice the broader implications of *Brüstle*. By ascribing dignity, not to say sanctity, to the fertilized egg, the decision might be said to align the moral compass of patent law with the most conservative ethical tendencies in Europe (for a survey of European attitudes see Gaskell *et al*., 2012). So, the price of applying the logic of *Brüstle* to the case of TLM might be to lend symbolic reinforcement to these conservative positions. If only for that reason, courts might be reluctant to accept the interpretation of *Brüstle* that is proposed here. But even if the argument here fails as a means of opposing the patenting of time-lapse microscopy, it would still have the merit of forcing greater clarity in the specification of the quality of dignity that European patent law attributes to embryos.

References

Armstrong et al, Time-lapse in the IVF-lab: how should we assess potential benefit? *Human Reprod* 2015; 30: 3-8.

Basile et al, Time-lapse in the IVF-lab: how should we assess potential benefit? *Human Reprod* 2015; 30: 1276-1278.

BBC Scotland, 'First baby conceived with time-lapse imagine IVF born in Glasgow', 14th June 2013. At: http://www.bbc.co.uk/news/uk-scotland-22910864. Last accessed July 4th 2017.

Brüstle v *Greenpeace* (Brüstle) (C-34/10) [2011] E.C.R. I-9821.

Cohen, 'On patenting time and other natural phenomena' (2013) 27:2 *Reproductive BioMedicine Online* 109-110.

EPO, Plant cells/*PLANT GENETIC SYSTEMS* (1995) OJ EPO 545.

Gaskell, Stares, and Pottage (2012), 'How Europe's ethical divide looms over biotech law and patents' *Nature Biotechnology*, 30 (5). 392-394.

GRCM, 'Time-lapse imaging'. At: http://www.gcrm.co.uk/treatments/time-lapse-imaging/ Last accessed July 4th 2017.

Habermas, *The Future of Human Nature* (2003).

Hansard (House of Lords), Written answers, 8 January 2013.

Kieslinger et al, 'Embryo selection using time-lapse analysis (Early Embryo Viability Assessment) in conjunction with standard morphology: a prospective two-center pilot study' (2016) *Human Reproduction* , advance access

Mirowski, *Science-Mart. Privatizing American Science* (2011).

Pearce, 'Time-lapse microscopy patent upheld in Europe' (2017) 34 *Reproductive BioMedicine Online* 169-171.

Reijo Pera, 'More than just a matter of time' (2013) 27:2 *Reproductive BioMedicine Online* 113-114.

Sperling, *Reasons of Conscience. The Bioethics Debate in Germany* (2013).

Sterckx, Cockbain and Pennings, 'Patenting medical diagnosis methods in Europe' (2017) 34 *Reproductive BioMedicine Online* 166-168.

Declaration

The author reports no financial or commercial conflicts of interest.