Chapter 21

ON THE ETHICAL FOUNDATION OF PROPRIETARY RIGHTS: COVID-19, PUBLIC HEALTH, AND THE LIMITS OF PATENTS IN THE EUROPEAN CONTEXT

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1. Introduction

In mid-March 2020, Nunzia Vallini – a journalist working for a local newspaper in Brescia, a city in northern Italy – got in touch with Cristian Fracassi, engineer and chief executive of Isinnova, a 3D printing start-up.[1] The hospital in Brescia, which would sadly become famous as one of the European epicentres of the pandemic, saw a spike in hospital admissions due to COVID-19 infections in that period. The number of patients needing intensive care skyrocketed to 250 in just a few days, and the hospital was running out of respirator valves, with the official supplier unable to meet the sudden demand. The valve, originally produced by UK manufacturing company Intersurgical which owns patent rights protecting such a technology, allows ICU patients to be connected to breathing machines. The design enables a maximum eight hours of use, therefore requiring frequent replacement.

In collaboration with engineer Alessandro Romaioli, Isinnova reverse-engineered the valve, after Intersurgical apparently refused to share the schematics of the product.[2] The release of the 3D printed version of the reverse-engineered valves started immediately after the first positive trial. Time was in effect of the essence: many were already dying as a consequence of COVID-19 complications, and in Italy would claim at that moment 45,000 lives[3] (at the time of writing, the death toll in Italy has exceeded 95~~0~~,000). "We're trying to save lives," Fracassi replied during an interview with *BBC News*, which was instrumental in bringing this case into the media spotlight for having highlighted a potential patent and public health issue.

In effect, early reports of the news suggested that Intersurgical was ready to go to court, threatening to sue Isinnova for patent infringement. Amidst public outcry, Charles Bellm – managing director of the UK company – later issued a statement claiming that his group had never considered a lawsuit. "[W]e were contacted at the end of last week for manufacturing details of a valve accessory," Bellm said, "but could not supply these due to medical manufacturing regulations, we have categorically not threatened to sue anyone involved".[4]

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[1] Zoe Kleinman, 'Coronavirus: 3D Printers Save Hospital with Valves', *BBC News*, 16 March 2020.

[2] Jay Peters, 'Volunteers Produce 3D-Printed Valves for Life-Saving Coronavirus Treatments', *The Verge*, 17 March 2020.

[3] Gianfranco Alicandro, Giuseppe Remuzzi, and Carlo La Vecchia, 'Italy's First Wave of the COVID-19 Pandemic Has Ended: No Excess Mortality in May, 2020', 396 *The Lancet* 10253, 12 September 2020, available at: < e27–28, https://doi.org/10.1016/S0140-6736(20)31865-1 >.

[4] Jay Peters, 'Volunteers Produce 3D-Printed Valves for Life-Saving Coronavirus Treatments' *The Verge*, 17 March 2020.

2. Patent protection in Europe and the ethics of pandemic litigation

The Italian case was only one among the many similar controversies in intellectual property (IP) protection that emerged internationally.[5] How things actually unfolded in this story (and other similar ones) is somewhat irrelevant here: what is important is a more general question about the ethics of IP that the story raises. If Intersurgical had decided to sue Isinnova, such a legal move would have been perfectly legal: but would have that been a morally justifiable action? And, by bringing this doubt into the legal domain, should European laws accept or ignore claims of IP infringement in extreme circumstances such as a pandemic?

It should be noted as a preliminary matter that patents are strongly protected in Europe. The European Patent Convention (EPC), which is not an EU instrument,[6] provides a solid legal framework for the granting of European patents. Pharmaceutical companies from all over the world regularly obtain European patents to protect a wide range of new medicines – which they use to recoup the (often huge) investments necessary to develop them. Patent protection is therefore key to the pharmaceutical industry, also in Europe. This also clearly emerges from the recent European Parliament Resolution 'The EU's Public Health Strategy Post-Covid-19' of 10 July 2020.[7] While the Resolution calls on the Commission and the Member States to allow maximum sharing of COVID-19 health technology-related knowledge, IP and data to the benefit of all countries and citizens (Paragraph 6), on the other hand it also reminds us that the EU must keep a robust European IP regime to incentivise research, development, and manufacturing, to make sure that Europe remains a world leader in innovation (Paragraph 23).

With that being said, one could argue that behaviours seemingly disregarding the imminent death of many individuals as well as the concrete possibility of further spreading of a dangerous virus appear morally disputable. Patents, one may very well add, should not make access to drugs or life-saving technologies more difficult, especially during a pandemic. Should we allow for restrictions of circulation of knowledge and its outcome to increase profits in times of a health crisis? The COVID-19 pandemic has taught us many things, but when looking at patent laws, perhaps its most important lesson has to do with the ethical justification of IP. Put in a nutshell, IP protection cannot be fully or effectively vindicated by egoistic theories.[8] In other words, personal gain – broadly understood both as existential self-realisation[9] or

[5] For a discussion of international patent controversies during the pandemic, see for instance Enrico Bonadio and Andrea Baldini, 'COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health', 11 *European Journal of Risk Regulation* 2, pp. 390–95, available at < https://doi.org/10.1017/err.2020.24 >.

[6] European Patent Convention (Convention on the Grant of European Patents) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000. The EPC has been signed by 38 Contracting States, including countries which are not EU Member States.

[7] European Parliament Resolution 2020/2691(RSP) 'The EU's Public Health Strategy Post-Covid-19' of 10 July 2020.

[8] For an instructive survey of philosophical justifications of intellectual property, see Adam Moore and Ken Himma, 'Intellectual Property', in *The Stanford Encyclopedia of Philosophy*, Ed. Edward N. Zalta, Winter 2018 (Metaphysics Research Lab, Stanford University, 2018), available at < https://plato.stanford.edu/archives/win2018/entries/intellectual-property/ >.

[9] Georg Wilhelm Friedrich Hegel, *Elements of the Philosophy of Right*, Ed. Allen Wood, Cambridge: Cambridge University Press, 1991.

economic profit[10] – does not offer solid moral ground to justify IP in extreme and urgent situations such as those produced by the COVID-19 crisis. And egoistic takes on IP justifications clearly show their limits when major conflicts between individual and societal well-being emerge. The many months of global lockdown have been a powerful reminder of a simple truth about humans: we are a community of unity, whose collective well-being also makes individual self-satisfaction possible.

3. The relevance of collective well-being: should patent rules be relaxed?

After all, collective well-being was taken into consideration by the German judiciary when a compulsory licence over a patent owned by the Japanese company Shionogi was granted to Merck in 2017. While controversial, compulsory licences allow eligible drugmakers to legally manufacture and sell generic versions of patented drugs during national emergencies, public health crises, or in other instances of extreme need. In that case the German Federal Patent Court granted Merck the compulsory licence to continue selling the HIV drug Isentress, which contains the patented active ingredient raltegravir.[11] The decision was also confirmed by the German Federal Supreme Court shortly after.[12]

The grant of the compulsory licence was preceded by a patent infringement claim brought by Shionogi (owner of the European patent over the raltegravir) against Merck before the District Court of Duesseldorf in 2015[13] after licence negotiations between the parties were unsuccessful. The Japanese company sought, *inter alia*, an injunction preventing Merck from using raltegravir in their drugs. The court stayed the suit pending the opposition proceedings against Shionogi's European Patent initiated by Merck before the European Patent Office.[14] In the meantime, Merck applied for the grant of a compulsory licence before the German Federal Patent Court. As Shionogi objected to the claim brought forward, Merck requested the Court to grant the compulsory licence by way of a preliminary order. The request was lodged pursuant to Section 85 of the German Patent Act. This provision allows compulsory licences to be granted as an interim measure where the applicant is able to furnish evidence that the prerequisites for granting a compulsory licence as outlined within Section 24(1)-(6) of the Patent Act are given and that an urgent public interest in granting the licence exists. In this specific case, the licence was granted because the health of many people was at risk, including that of pregnant women, infants, young kids as well as newly infected and long-term patients.[15] In particular, it was held that the public interest justified the compulsory licence, also taking into account the effects that an injunction against Merck would have created for HIV patients. The German Federal Supreme Court's release clarified as follows:

[10] John Locke, *The Second Treatise of Government*, Ed. Peter Leslett, Cambridge: Cambridge University Press, 1988.

[11] Decision of 11 July 2017; X ZB 2/17, GRUR 2017, 1017.

[12] Decision of 21 November 2017; 3 Li 6/16, GRUR 2018, 803.

[13] Landgericht Düsseldorf (4c O 48/15).

[14] The patent was subsequently revoked by the EPO Board of Appeals in 2017 - EPO, Technical Board of Appeal 3.3.01, T 1150/15, decision of October 11, 2017 – Merck & Co., Inc. v. SHIONOGI & CO., LTD.

[15] Christof Hohne, 'Compulsory Licences in Germany: A Tool for Licensing Negotiations?', *European Pharmaceutical Review*, 8 March 2019, available at < https://www.europeanpharmaceuticalreview.com/article/84768/compulsory-licenses-in-germany-a-tool-for-licensing-negotiations/ >.

> 'The Federal Court also shares the assessment of the Federal Patent Court that a public interest in the granting of a compulsory licence is credible. It is true that not every HIV or AIDS patient is required to be treated with raltegravir at any time. There are, however, patient groups that needed raltegravir to maintain the safety and quality of treatment. These include, in particular, infants, children under 12, pregnant women, people who need prophylactic treatment because of the risk of infection, and patients who are already treated with Isentress and who are threatened with significant side effects and interactions when switching to another drug'.[16]

This German case is certainly exceptional. There are no (recent) reported decisions in Europe where compulsory licences of pharmaceutical patents have been granted. Yet, this example shows us something important: the *public* need to access important life-saving medicines may in some specific circumstances override the *private* interests of patent owners in restricting such access (indeed, as patents constitute monopolies, their owners are usually able to charge higher prices for their patented products and thus restrict availability). The collective good thus may supersede the financial interests of specific companies. Also, it seems that several sectors of society and politicians in Europe are pushing the argument that the current COVID-19 global emergency justifies the relaxation of patent and other IP rights over medical technologies useful to fight the virus.[17] It will certainly be difficult to soften the traditionally pro-IP stance adopted by the European Commission and in general by EU institutions. Indeed, together with the US, UK, Switzerland and other industrialised nations, the EU strongly opposes the temporary international waiver on TRIPS obligations[18] for all coronavirus-related medical products, including vaccines, proposed by India and South Africa,[19] preferring instead voluntary licensing of IP to promote equitable and global access to such products. Yet, the unprecedented health emergency that Europe is facing, with the death toll still increasing and uncertainties growing over whether new COVID-19 variants are more infectious, may trigger a rethink of the current IP maximalist policy.

Recent trade tensions between the EU and UK regarding exporting vaccines have added a further political layer to the complex relationship between public health and corporate profit. As an outcome of what can be rightfully described as a scientific miracle, several vaccines independently produced by different pharmaceutical companies have become ~~recently~~just available. The last one to be approved by the EU is the AstraZeneca vaccine, following Pfizer-BioNTech and Moderna.[20] In early February 2021, the European Commission backtracked on its early decision to apply an emergency provision included in the Brexit deal to block vaccine exports to the UK, at a time when Europe suffers from a shortage of the medicine that could

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[16] The translation has been taken from a blogpost by Andrew Goldman, 'German Federal Supreme Court Affirms Compulsory License on HIV Drug', published in the Knowledge Ecology International (KEI) website on 13 July 2017, available at < www.keionline.org/23403 >.

[17] Ashleigh Furlong and Sarah Anne Aarup, 'Europe hints at patent grab from Big Pharma', *Politico*, 3 February 2021.

[18] TRIPS Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994). This World International Organization treaty provides minimum standards of IP protection at global level.

[19] Ann Danaya Usher, 'South Africa and India push for COVID-19 patents ban', *The Lancet*, 5 December 2020.

[20] 'Covid: EU approves AstraZeneca vaccine amid supply row', *BBC News*, 29 January 2021.

stop the pandemic.[21] Here trade regulations seem to be bent in order to serve specific political interests.

4. Conclusion

In ethical theory, altruistic forms of consequentialism offer a suitable philosophical framework that could capture these exceptional cases, thus providing us with a more robust justification of IP that balances individual and collective needs and concerns.[22] While recognising the ethical relevance of egoistic demands, altruistic consequentialism places those within a larger altruistic framework whose final horizon is societal utility. Traditionally, altruistic consequentialism has offered justifications based on the collective gain that follows from offering people incentive for innovation.[23] By rewarding the efforts of certain ingenious individuals, IP protection has been considered a powerful stimulus to creativity, the consistent exercise of which appears to be instrumental in maximising social utility, which is the key principle of altruistic consequentialism.

But conventional altruistic consequentialism is inadequate insofar as it conceptualises innovators in terms of individual subjects, which could be either persons, institutions, or companies. And yet, at a time where scientific cooperation is at one of its historic peaks, we cannot fail to witness and acknowledge once again that the logic of discovery is of a distributive kind: innovators are likely to be collective rather than individual subjects, and laws should find ways to protect the possibility of collaboration. This in turn seems at odds with commonsensical takes on IP, but it is certainly a welcome implication of altruistic understandings of patents.

Balancing altruistic and egoistic motives in innovation is certainly difficult – and there is no exact science to that. Prudence and tact are essential requirements of effective management of IP protection. Especially when dealing with public health emergencies of a global scale such as the COVID-19 pandemic, profit may very well have to bow to ethical or moral concerns. There is no denying that IP laws play a generally significant role in promoting research with positive societal impact, but they are not flawless, and we should not exclude a need for reform to meet these new challenges. The key is to lay out conditions for strengthening the mutual trust that international public health cooperation requires.

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[21] 'EU vaccine export row: Bloc backtracks on controls for NI', *BBC News*, 30 January 2021.

[22] In ethical theory, altruistic consequentialism is usually called utilitarianism. In this context, we opt for this alternative terminology ('altruistic consequentialism') to avoid a potential ambiguity with what is known as the 'utilitarian theory' of IP (i.e., IP rights represent an encouragement from the State for the production of inventions and cultural products useful to society).

[23] Tom G. Palmer, 'Are Patents and Copyrights Morally Justified - the Philosophy of Property Rights and Ideal Objects Symposium on Law and Philosophy', 13 *Harvard Journal of Law & Public Policy* 3, 1990, pp. 817–66.