Basic and Improvement Patents in COVID-19 Vaccines

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Short title : Editorial

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While measures to disseminate COVID vaccine patented technologies (compulsory licences, waives, etc.) are often discussed [cf. Andreas Oser, 'The COVID-19 Pandemic: Stress Test for Intellectual Property and Pharmaceutical Laws', GRUR International 2021, 846 ff.], a less examined issue is the relationship between basic and improvement patents in this field.

Enhanced technologies are frequently released due to the increasing incremental innovation model. Examples of such improvements are not only enhancements, but also – in a broader sense – new uses or side-shift functions of a basic invention in another field or a combination of two or more prior inventions. As a consequence, two main questions arise: (1) whether the improved technology is patentable in spite of the basic (or another prior overlapping) patent; and (2) if so, when patentees are different, whether the second patent can be exploited without infringing the basic (or another prior overlapping) patent still in force.

As for the first question, an affirmative answer is commonplace, since no particular issue arises on improvements. This conclusion is supported by an epistemological viewpoint since no invention has ever been made from nothing, but all of them are in one way or another 'derivative' as enhancements, side-shift functions or combinations of prior art [Richard Sennett, 'The Craftsman', Yale Univ. Press, 2008].

Accordingly, 'when considering patentability of an improvement, the entire disclosure of the basic patent is reviewed in order to ascertain whether there are meaningful technical differences between the disclosure of the basic patent and the improvement. If there are technical differences, the improvement has requisite statutory novelty. The next test regarding the inventive step is whether the differences between the improvement and the disclosure of the basic patent are such that one skilled in the art to which the improvement relates would find the differences obvious at the time the invention was made. If such differences are obvious, then the improvement is not patentable'. On the contrary, if unexpected beneficial properties are obtained, 'these differences and others can contribute to patentability' [Arnold B. Silverman, 'The Relationship Between Basic and Improvement Patents',

(1995) 47 JOM 50 ff.].

As for European law, see Art. 54(4) European Patent Convention (new compositions and substances for another use) or EC Directive No. 98/44, on biotech inventions: 'this Directive does not in any way affect the basis of current patent law, according to which a patent may be granted for any new application of a patented product' (see Recital No. 28).

Concerning the second question, on the other hand, the common opinion is negative. Every patent grants the right to prevent others from making, using or selling the patented invention. As a consequence, 'in many instances, a patented improvement cannot be made, used, or sold without infringing the basic patent' [ibid.].

This rule is also laid down in Art. 68(2) of the Italian Code of Industrial Property as well as in Art. 2587(1) of the Civil Code, repeating the same provision of the 1939 Patent Act stating that 'A patent for an industrial invention, whose implementation implies that inventions protected by earlier patents for industrial inventions are still in effect, may not be implemented or used without the consent of the owners of the latter'. The plural 'inventions' confirms that a new patent can incorporate two or more earlier patents. This is what happens by definition in a combination. But in this case too, the rightholders of the prior patents will have to agree to the use of the new invention.

The same rule applies worldwide to 'derivative works' under copyright law. These enjoy protection as long as they meet the originality requirement, but 'without harm to the copyright in the prior work'. Since copyrights and patents are incentives to literary, artistic or technical innovation, this is deemed to be the optimal solution for rewarding both innovators.

However, this solution is based on an optimistic view, according to which patentees will find an agreement in their mutual interest so that the second patentee will be able to put its patent into use, in the same way as it is expected that the market will strike a reasonable balance between supply and demand. Therefore, someone that is more skeptical regarding such optimism in the face of so many market failures, may note that a prior inventor may have opportunistic reasons not to enter into an agreement: insufficient fees or compensation in case of license or assignment; loss of sales on the prior invention; chances for a competitor to increase its market share, etc.

In these cases, improvement patents remain like flowers in a park: look but don't touch. Thus, a prior patent becomes a 'blocking patent' in spite of incentives for technical dissemination and social welfare, which ~~is~~are ~~the~~ counterpart of the patent system *rationale* [Robert Merges, 'Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents', (1994-95) 62 Tenn. L.Rev. 75 ff.].

This optimistic perspective is also challenged by Art. 31(l) TRIPS, which provides for compulsory

licences in some circumstances (such as failure to work or insufficient working) among which is expressly mentioned 'to permit the exploitation of a patent (the second patent) which cannot be exploited without infringing another patent (the first patent)' when the first patentee has refused to deal, notwithstanding reasonable commercial terms and conditions have been offered [Gustavo Ghidini, 'Intellectual Property and Competition Law, The Innovation Nexus', E. Elgar 2006, 24 ff.].

This remedy remains, however, unsatisfactory. The measure is constrained by too many procedural steps and uncertain clauses, that can be disputed in trial for long time, thereby hindering the interest in the licence for the obsolescence in the prior technology before a final decision [cf. Svetlana Krupko, 'Compulsory Licensing in the Case of a Dependent Patent: The Interplay between Intellectual Property Law and Civil Law', GRUR International 2021, 1023 ff.].

Even if negotiations required by Art. 31(b) may be waived during emergencies – which is certainly the case in the COVID pandemic – the additional requirement in Art. 31(l)(i) is difficult to be satisfied in any case. Indeed, it can also be contradictory that an invention claimed in the second patent should involve 'an important technical advance' in relation 'to the invention claimed in the first patent', because – first of all – this top-level inventive step should imply in turn a very enhanced technology and a more 'autonomous' independent patent rather than a 'derivative' one. Secondly, Art. 31(l) also prevents compulsory use such as highly technical upgrades when their 'economic significance' is not 'considerable', lacking here any social perspective as opposed to an economic magnitude. With respect to COVID vaccine patents, for example, a relevant deletion of rare side effects for some uncommon, but severe collateral diseases, might not be profitable enough.

This provision seems also to prevent other exceptional measures, such as the ones foreseen by Art. 30 TRIPS. However, the essential *rationale* of the patent system – fostering innovation as well as its dissemination – allows WTO members to take into consideration the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare and to a balance of rights and obligations (TRIPS Art. 7). While the mandatory nature of this provision is controversial, it seems undisputable that interpretations of patent law pursuing these objectives are consistent with the WTO legal system.

Accordingly, while provisions that are incompliant with the WTO Agreement cannot be enacted (Art. 8), a more balanced regime for 'inventing around' could in general be found by considering even smaller changes in structure and/or functions not only independently patentable, but also independently practicable as such, when the new function is more inventive/useful than simply non-obvious on its individual merits – *arg. ex* Art. 31(a) – even if its economic significance is limited. For example, allopurinol is a useful/inventive drug for decreasing blood uric acid levels. Its structure is, however, an isomeric analog to hypoxanthine (a naturally occurring purine) synthesized by switching the N_7 and C_8 atoms only. This suggestion may also be compliant with the European Patent Office's functional

'problem-solution approach'.

By this interpretation, prior consent and Art. 31(l) TRIPS would come into consideration only in case of stricter technological 'dependency' – not of broader 'derivative' technologies – that nevertheless reveals important advances with considerable economic significance.

This subject-matter is very relevant for COVID vaccine patents, where a complex network of overlapping and enhanced technologies by different patentees creates a very tangled web [Mario Gaviria and Burcu Kilic, 'A network analysis of COVID-19 mRNA vaccine patents' in Nature Biotech., 39, May 2021, 546 ff.].

For example, both Pfizer and BioNTech were sued for the use of a patented fluorescent protein in developing their vaccines, but the case was settled 'in a mutually satisfactory manner' according to the optimistic theory [see S.D.Cal., 4 May 2021, *Allele Biotechnology and Pharmaceuticals, Inc. v. Pfizer, Inc*. No 3:20-cv-01958; Blake Brittain, 'Pfizer, biotech firm end patent fight over COVID-19 vaccine', Reuters, 6 January 2022].

Also, Moderna could face infringement issues since a Federal Court opinion has partially rejected its challenge to two of Arbutus Biopharma Corp.'s prior patents on December 2021. The 'patents in question involve the so-called lipid nanoparticles that enclose the genetic material, known as messenger RNA (mRNA), in the vaccine', which 'could prove useful in developing future mRNA-based vaccines against other illnesses as well' [Brendan Pierson, 'Moderna could be sued over vaccines as Court upholds Arbutus patents', Reuters, 1 December 2021. As for the opinion, see <https://cafc.uscourts.gov/opinions-orders/20-1184.OPINION.12-1-2021_1872445.pdf>, following P.T.A.B., 11 September 2019, *Moderna Therapeutics, Inc. v Protiva Bio-therapeutics, Inc*., IPR2018-00739, and P.T.A.B., 23 July 2020, Moderna Therapeutics, Inc. v Arbutus Biopharma Corp., IPR2019-00554].

Furthermore, the National Institutes of Health owns a technology on the prefusion of COVID-19 spike proteins and their use, which is necessary to make plenty of vaccines and had been licensed to BioNTech. In turn, Moderna dropped a patent application for encouraging an agreement with the NIH after the latter had alleged joint inventorship in some Moderna's mRNA-1273-related patents [Hannah Gannage-Stewart, 'Moderna withdraws patent application in NIH talks', Intellectual Property Magazine, 22 December 2021; T. J. Mantooth, 'Inventing Chaos with the Moderna/NIH Dispute', IPWatchdog, 6 December 2021].

However, in 2020 Moderna stated that there was 'uncertainty about which patents will issue, and, if they do, as to when, to whom, and with what claims', so being 'possible that one or more organizations will hold patent rights to which we may need a license, or hold patent rights which could be asserted against us', even though Moderna finally affirmed that it was 'not aware of any significant

intellectual property impediments for any products we intend to commercialize, including mRNA-1273'. Moderna also stated that it did to not want to enforce its patents against competitors during the pandemic, but, in turn, the company was open to licensing its technology only afterward [Eric Sagonowsky, 'Moderna won't enforce COVID-19 vaccine patents during pandemic', FIERCE Pharma, 8 October 2020].

Another solution in case of a worldwide pandemic could be, of course, a 'Sabin' model. While it is, however, difficult that biotech companies (even if publicly funded) may grant licences to competitors when contrary to their policies or interests and Art. 31(l) is not applicable, a new COVID vaccine (*Corbevax*) is being developed in Texas through a decades-old conventional method that will make it patent-free, not only resulting in more production and dissemination as such, but with the intention to set an open-science pattern for improvements [Erum Salam, 'Texas scientists' new COVID-19 vaccine is cheaper, easier to make and patent-free', The Guardian, 15 January 2022; generally Matthias Leistner, 'Towards an Access Paradigm in Innovation Law?', GRUR International 2021, 925 ff.].

Time will tell.

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