

Stoccolma per Marianne

Which innovation is worthy of patent protection in the era of incremental innovation?

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1 THE INFLUX OF INCREMENTAL INNOVATION

Long, long “gone are the days” of the XIX parameter of a ‘flash of genius’ to define the qualitative level of an innovation deserving of a patent.

That parameter went out, as known, due to the evolution of modern R&D dynamics, chiefly consisting (unlike the groundbreaking ones of the first industrial revolution) in painstaking processes made up of progressive even small but quite costly steps carried on by trial and error (J. Reichman) by complex teams of specialist researchers, working with sophisticated computing and scientific equipment.

No wonder, then, that a clear tendency emerged and became established in favor of lenient criteria of patentability, so as to include the fruits of *incremental innovation*.

This took place progressively.

The classic regime dictated two distinct substantial requirements for a valid patent, which expressed the innovative nature of the invention: *novelty* in the historical sense (‘extrinsic’ novelty), namely objective differentiation from known technical solutions; and *originality* (‘intrinsic’ novelty), namely the objective inventive step ahead of the body of existing knowledge, i.e. the prior art.¹

The interpretative development which led to the 1974 European Patent Convention and the ensuing national legislations, recognized that a given solution is original (‘involves an inventive step’) only ‘if, having regard to the state of the art, it is not obvious to a person skilled in the art’ (article 56 of the EPC). The *Note* to article 27(1) of the TRIPs Agreement, which is an integral part of the text thereof, follows the same line: ‘inventive step’ is defined as being synonymous with ‘non-obvious’.

In other words, achieving an *objective* progress vis-à-vis prior art (while evoking a broad societal rationale of patent protection, and being the object of a disclosure duty by the applicant, ex Rule 42c, Regulation to EPC) does not as such constitute, according to the dominant interpretation, a requirement for patentability. It neither defines or complements the statutory requirement of ‘non-obviousness’. The assessment of an ‘important technical advance of considerable economic significance’ as positive legal

requirement is relevant *only* in the context of the special regime granting a compulsory (cross-) license under the provision of art. 31(1) TRIPs.

2 CONTEMPORARY ‘INDULGENCE’, AND ITS COROLLARIES

Thus, at the end of the day, exclusive protection is also granted to innovations of modest ‘originality’, provided that the innovation cannot be easily deduced from the prior art by a person skilled in the art.² An approach that could ultimately lead to the requisite of non-obviousness being substantially absorbed by that of objective novelty (and not vice versa, as would be more logical).³

As a rather obvious consequence of the reduced selectivity of access to patents, it becomes relatively easy for competitors to ‘elude’ the exclusionary rights of the patent holder. In fact, the modest degree of originality deemed sufficient to obtain a patent would more easily allow distinct solutions to be classed as ‘non-equivalents’ (not mere variations implementing the same idea solution), hence more easily obtain an independent (‘free’) status – including their own independent patentability. Indeed, ‘For the purpose of determining the extent of protection conferred by a [European] patent, due account shall be taken of any element which is equivalent to an element specified in the claims’ (Protocol on the Interpretation of Article 69 EPC of 5 October 1973, n.2).

In sum, the assessment of ‘inventive character’ and that of actual infringement are closely connected: if the invention is ‘non obvious’, it is not, by definition, ‘equivalent’ to a previous one, thus does not infringe it. Now, as hinted, a ‘loose’, low-key assessment of inventiveness will logically correspond to a generous evaluation of ‘non-equivalence’ of the subsequent innovation. The author of the latter will more freely enter the market with her own solution (provided that this does not merely reproduce the prior patent). A result which would obviously be hampered if the prior patent were given broader protection based on a more ‘expansive’ assessment of ‘equivalence’.⁴

Is this, as one might at first sight infer, a positive result in terms of enhancement of dynamic competition (competition by innovation)? Let’s not be hasty. Some further analysis is called for in the light of a rethink in growing

areas of the legal (and business) world as to the level of inventiveness that should be required for granting a patent.

3 RISKS VIS-À-VIS THE FOSTERING OF DYNAMIC COMPETITION.

From about twenty years, in both Europe and the United States, a rising chorus of concern has critically commented the evoked trend to facilitate access to patents, favoring ‘the eagerness of even wise and able men to establish their priority in an unimportant discover’⁵.

Please don’t get me wrong here. The need to adapt the patent system (that is, protection of R&D against free riding) to the predominantly incremental nature of contemporary innovation is not being called into doubt. Rather, it is a question of degree. Incremental, as the very word itself (and economists) suggests, means to work on the results obtained by those who went before. It does not and must not mean ‘insignificant’.⁶ Now, a legitimate doubt has grown that the evoked trend has gone too far in concrete terms so as to pose grave risks for a lively dynamic competition.

Here, the first and most immediate risk is that of scattering the path of subsequent innovators with others’

undeserving, negligible (‘poor quality’) patents, acting as arbitrary legal barriers, difficult and costly⁷ to remove: with the ultimate effect of slowing down and discouraging technological progress. This risk becomes higher when a *patent thicket* is strategically used in order to hinder current or emerging minor competitors⁸ – either by delaying their entrance into the market or imposing costly ‘settlements’ under the threat of a judicial offensive.⁹ (That risk exponentially increases when patent thickets are held by dominant undertakings: which is more and more typically the case in ‘innovation markets’).

A second risk, linked to the first one, is more subtle but no less serious. I am referring to the possibility that thanks to a very slight change, at times a question of semantics consisting of a mere ‘clever turn of the phrase’¹⁰, the holder of a patent successfully resorts to the ploy of obtaining patents for subsequent *improvements* (that is, objectively derivative but held by the same person) in order to surreptitiously extend the length of the original exclusive rights beyond the statutory period of efficacy. This risk is indeed a real one, as confirmed by the widespread practices of so-called ‘evergreening’. For example, the filing patents that protect mere equivalents of the *main* patent nearing expiry, is a quite frequent *manoeuvre*,

¹ The validity of a patent presupposes from a substantive viewpoint that the invention entails a solution to a technical problem not yet resolved and is capable of industrial application such as to advance prior art and existing knowledge (*extrinsic novelty*) and is also an expression of a creative effort on the part of the inventor that is not just the mere execution of already known ideas falling within the normal application of known principles (*intrinsic novelty*).

² Although it can well be, in the specific case, a factual indicator of non-obviousness. On the subject see the in-depth essay by Hanns Ullrich, ‘Standards of Patentability for European Inventions: Should an Inventive Step Advance the Art?’, *IIC Studies in Industrial Property and Copyright*, 1, 1977. May I add (in possible disagreement, here, with Ullrich, *ibid.*, at 99 and fn 6) that ‘useless’/‘frivolous’ inventions can well be ruled as unpatentable on the basis of a serious application of the requirement of ‘industrial applicability’. See also R. Eisemberg, ‘Obvious to Whom? Evaluating Inventions from the Perspective of the PHOSITA’, *Berkeley Tech L. J.*, 2004, 885, in a comparative perspective, as offered by J. Bochovic, ‘The Inventive Step: Its Evolution in Canada, the United Kingdom and the United States’, *IIC Studies in Industrial Copyright and Copyright Law*, vol. 5, 1982. It is also worth considering the Italian Supreme

Court’s decision no. 13863 of 11 December 1999 (*Giur. Dir. Ind.*, 1999, p. 115), cited by Italian Supreme Court judgment no. 17993 of 9 September 2005 (*Foro It.*, 2006, I, 11), according to which patentability does not require any progress against a preceding invention aimed at solving the same problem: what is relevant is that it (the second invention) pursues said function with a different (and novel) technical solution.

³ The judgment that a discovery is not obvious from the state of the art logically absorbs the preliminary one that it is not obvious across the board from that state. So much so that the contrary is impossible. Formally concentrating on the sole requisite of non-obviousness would serve not so much probably to simplify the procedure (the state of the art would still need to be preliminarily checked) but more to place greater emphasis on inventiveness and so in general raise the bar of non-obviousness beyond ordinary invention.

⁴ The risk of extending the patent monopoly beyond what has been effectively invented by broadening the concept of ‘equivalent’ (especially in order to protect ‘pioneer inventions’, in which the breadth of the concept of equivalence translates into a ‘hunting licence’ over the derivative innovation in favour of the pioneering inventor, following the line in *Graver Tank and Mfg. Co. v. Linde Air Prods. Co.*, 339 US

605, 1950), is emphasized by E. Steinhäuser, ‘Using the Doctrine of Equivalents to Provide Broad Protection for Pioneer Patents: Limited Protection for Improvement Patents’, *Pace L. Rev.*, 1992, 491.

⁵ J. Ruskin, *Sesame and Lilies: The Ethics of the Dust*, Preface to the Second Edition, reprinted, Oxford University Press, 1951, 15.

⁶ S. Scotchmer, ‘Standing on the Shoulders of Giants: Cumulative Research and the Patent Law’, *J. Econ. Persp.*, 1991, p. 29.

⁷ On this type of risk see A. B. Jaffe and J. Lerner, *Innovation and its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It*, Princeton University Press, 2006.

⁸ The remedy might consist in imposing heavy sanctions (along the lines of treble damages in the US) in favour of victims of sham litigation and above all expressly provide – at least in case law – that bringing such litigation may in itself constitute an act of unfair competition and even an antitrust violation in case the plaintiff enjoys dominant position.

⁹ *Ex multis*, see J. Bessen, M. Meurer, J. Ford, and J. Laurissa, *The Private and Social Costs of Patent Trolls* (19 September 2011), Boston University School of Law, Law and Economics Research Paper No. 11-45, available at SSRN: <http://ssrn.com/abstract=1930272> or <http://dx.doi.org/10.2139/ssrn.1930272>.

¹⁰ C. Bowe, ‘Merck Finds Tonic in Clever Turn of Phrase’, *Financial Times*, 29 March 2007.

especially in the chemical and pharmaceutical industries, in order to hinder/slow down the market entry of producers of generics.¹¹

To combat such risk a specifically narrow interpretation/application of the notion of *inventive merit*, and a correspondingly broad notion of *equivalence*, should be adopted. Even more so when, as in the example just made, the derivative innovation is accomplished by the same holder of the original patent: for her, who has conducted the original research, it is normally much easier to develop improvements.

This is indeed the lesson to be learnt from the well-known 2013 judgment of the Indian Supreme Court in the *Glivec* case,¹² where the Judges rejected an application to patent a derivative pharmaceutical invention for lack of significant progress in terms of therapeutic efficiency compared to the original drug, by then off-patent.

This sound lesson against ‘evergreening’ is worth to be treasured: but with an important caveat.

One should be cautious about entrusting to patent offices the assessment of the efficacy of drugs in attaining a certain therapeutic result. Here, please recall the general statement made above: that ‘inventive character’ (*and, a fortiori*, ‘novelty’) is no legal synonym of ‘economic or technical progress’. Hence, one should fully agree with the EPO’s approach, which, in relation to the claim of therapeutic effect, refers to an assessment in terms of ‘plausibility’. Right: no more than that. The ‘true’, ultimate assessment of therapeutic efficacy must be left (or however referred) to Public Health Authorities. This is to say that, beyond ‘plausibility’, patent offices should con-

centrate on the non-obviousness (strictly interpreted) of the invention: for this—not for preempting/substituting’ Health Authorities-- they are effectively equipped. Give Caesar...

4 SIGNS OF A RETHINK

However, as hinted there are objective signs of a rethink: on both sides of the Atlantic. As regards Europe, one must consider the amendments to the European Patent Convention (introduced by ‘EPC 2000’, entered into force on 13 December 2007), which, by reforming the procedure before the EPO, significantly extend the room for disputing applications and for appealing decisions.¹³

Equally interesting is the signal coming from across the Atlantic with the reform of US patent law made by the Leahy-Smith America Invents Act (AIA) 2011, which *inter alia* extends the deadline for pre-issuance submissions and introduced the possibility for any interested party to bring opposition proceedings to contest the validity of a patent after its granting.¹⁴ The reform was encouraged by many academics¹⁵ as well as the US Supreme Court that, in *KRS International Co. v. Teleflex Inc. et al.* (550 US 2007), warned the USPTO to raise the bar of non-obviousness above ‘ordinary innovation’;¹⁶ arguing that otherwise there was a risk that innovation might be stifled.¹⁷

5 THE CASE OF ‘STRATEGIC PATENTING’

The preceding hints to practices of ‘evergreening’ of near-to-expire patents evoke the broader subject of the so called “*strategic patenting*”. The term refers to a set of heteroge-

¹¹ The practice of extending the term of exclusive protection through improper filing of Supplementary Protection Certificates (SPCs) was the subject matter of the Italian case *Pfizer*, where the Competition Authority and the Council of State ruled that it constituted an abuse of dominant position to the detriment of generic drug manufacturers. See below, Chapter 5, section I.

¹² On 1 April 2013 the Indian Supreme Court rejected the appeal by the pharmaceutical company Novartis against a refusal to grant it an Indian patent regarding the beta crystalline form of its anti-cancer drug containing imatinib, whose commercial name was *Glivec*, applying domestic legislation, specifically article 3(d) of the Indian Patent Act amended in 2005 precisely with the intent of combating evergreening. The Indian Supreme Court judgment contrasts with that made by other patent offices that had addressed the issue like the EPO and the USPTO. On the matter, see R. Abbott, *Of Evergreening and Efficacy: The Glivec Patent Case* (29 April 2013), available at SSRN: <http://ssrn.com/abstract=2258904>; S. Basheer and T. Prashant Reddy, “‘Ducking”

TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)”, *National Law School of India Review*, 20, 2008, 131.

¹³ Among the most significant changes is the amendment [arts 105(a), 105(b) and 105(c)] envisaging a new centralized procedure whereby at the request of the proprietor, the European patent may be revoked or be limited by an amendment of the claims with effect in all Member States. Also worthy of note is the first paragraph of article 105, whereby any third party who is a party to infringement proceedings may intervene in opposition proceedings at any time.

¹⁴ See in particular 35 USC § 311 concerning the requests for *inter partes* re-examination and § 321 governing post-grant review.

¹⁵ Among the first to stress the need for legislative change was R. Merges, ‘As Many as Six Impossible Patents before Breakfast: Property Rights for Business Concepts and Patent System Reform’, *High Tech. L. J.*, 14, 1999, 577. The reform was also encouraged by a Federal Trade Commission study of 2003, *Report on How to Promote Innovation Through Balancing Competition with Patent Law and Policy*, available at: <http://www.ftc.gov/reports/promote-innovation-proper-balance-competition-patent-law-policy>.

gov/reports/promote-innovation-proper-balance-competition-patent-law-policy.

¹⁶ ‘... the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle rather than promote, the progress of useful arts’. And again, ‘... granting patent protection to advances that would occur in the ordinary course without real innovation retards progress ...’: *KSR Int’l Co. v. Teleflex Inc. et al.*, 550 US 2007.

¹⁷ There is nothing to prevent the ‘inventive character’ being expressed by a specific component of the overall new invention. This in particular with regard to nanotechnological inventions, where, as clearly pointed out by P. Errico, ‘La tutela brevettuale delle nanotecnologie’, *Riv. dir. ind.*, 2007, I, 61, the invention often encompasses a mix of different technical and scientific disciplines such as chemistry, physics, IT, etc. Inventions in which, it must be added, that character does not necessarily derive from the combination per se of those elements.

¹⁸ Thus, distinct from pay-for-delay agreements, a bi- or multilateral anti-competitive tort enforceable under art 81 Treaty.

neous unilateral¹⁸ conducts (often picturesquely named by managers and lawyers), essentially aimed at enriching the patent arsenal and its 'offensive' capacity—practices typically, albeit not exclusively, implemented by big companies. If said companies hold a dominant position, those conducts may amount to an antitrust tort (unprejudiced, of course, their possible relevance as straight violation of IP law rules). In systemic terms, this possibility amounts to a competition law's interference with the entitlement/acquisition itself – not just the 'exercise'—of IPRs.

This type/level of interference follows preceding stages of the saga of the intersection of antitrust with IP law. In the first one, soon after the enactment of the Treaty of Rome, antitrust principles were used by Commission and Court to check IPRs' holders power to stipulate agreements that, profiting from the statutory territorial reach of IPRs, ultimately partitioned the European market, thus contradicting the foundational objective of a Single Market. At a subsequent stage, that of the emergence of the essential facilities (EF) doctrine, antitrust eroded the IPRs holders' power –statutory power!—to exclude third not authorized parties from access to over-the-top, not workably substitutable (in this sense 'essential') technologies. This, in order to avoid that the patent might turn out an instrument for monopolizing a sector of industry, instead of a specific solution in competition with effective substitutes. Accordingly, the IPR holder who also detained a dominant position, became subject to a duty to license in favor of 'willing licensees'—the straight absolute exclusionary remaining intact vs. sheer, die hard free riders. The last (so far) stage is the one we are focusing on here: that of antitrust checking the entitlement itself of IPRs (*Astrazeneca*, e.g.) and/or its misuse thru illicit practices of strategic patenting.

As to the 'pattern-book' of said practices, I have just above evoked the so-called *product hopping*, i.e. the introduction and patenting, in approximation of the expiry of a basic patent, of new versions thereof, at times with pseudo-improvements in an attempt to 'evergreen' the exclusive position. One might also think of the so-called *patent hoarding*, i.e. the amassing of patents outside the patentee's firm technological line (patents, therefore, industrially 'useless' for the hoarder), but raked up either to prevent their purchase and exploitation by competitors, or for threatening minor competitors to stay out from the market 'or else' face a lengthy costly litigation—even a 'sham' one. Or of the creation of a dense network of patents - so-called *patent thickets* or *patent clusters* - concerning different formulations of the same invention, in order either to create uncertainty about the patent's scope or-- in the case of continuous filing of secondary applications--- about the duration of exclusive protection. And so on and so forth.

Taken together, these and other similar practices are the ultimate result of two main combined factors. One, economic, is the tendency towards concentration, particularly intense in the 'advanced' markets, including the pharmaceutical one (and that of digital media), constantly moving towards oligopolistic structures, and where com-

petition thru IPRs is particularly acute. The other is scientific and technological, and consists in the slowdown, more intense in certain sectors, of 'cutting-edge' innovation. It has been decades, for example, since effective antibiotics against new resistant strains of bacteria were developed.

The joint effect of these two factors is the pressure put on firms and groups, especially the big ones, to obtain as much IP protection and to 'squeeze' the IPRs attained as much and as long possible.

6 FOLLOWS: SEPARATING THE WHEAT FROM THE CHAFF.

From a legal point of view these practices frequently make use of faculties per se granted by IP legal regime. Hence the borderline between lawful activities and conduct amounting to an 'abuse' is often thin (save for striking cases, such as the provision of misleading information to the patent Office, or the promotion, for 'blackmailing' purposes, of sham litigations). That borderline must therefore be sought with a cautious, Aristotelian attention to the specific circumstances of the single case – also because the abusive conduct is at time quite 'simple'



(as in *Astrazeneca*), at times is an astute complex manoeuvre to be carefully reconstructed, as in the Italian *Pfizer* case.

(May I emphasize that the specific circumstances I'm referring to should be just *objective* ones. The intention to destroy competitors is permanently, I'd say physiologically, associated with the struggle for the market, so the interpret should not waste her/his time about 'intentions').

Thus, for example, with respect to cases of 'hoarding' competition authorities and Courts should give green light to conducts whereby the patents are actually raked to strengthen the core business of the patent holder (which certainly cannot be prohibited: except in the case of mergers, in the present stage of positive antitrust law firms cannot be prevented from 'overgrowing'). On the other hand, red light should be given when the hoarding concerns patents that a company of superior financial means does not actually employ nor is preparing to employ in its own business, but just uses them (e.g. by engaging, thanks to its 'deep pockets', in costly sham litigations) to cut the grass under the feet of rivals of minor financial means, who are engaged in the search for substitute technologies.

Similarly, I would be wary of outright condemning product hopping in case a patent is sought on a new mode of administering a drug, before checking whether the proposed new method is a Dulcamara hotchpotch¹⁹ rather than, as is the case with certain chemotherapics, an effective albeit incremental means of 'slow release' that enhances the therapeutic efficacy or reduces the discomforts associated with assuming a certain type of drug. And so on.

7 AN OVERALL RATIONALE: FOSTER 'TRUE' INNOVATION

The specific rationale for enforcing abusive forms of strategic patenting is quite evident. It is a policy that aims to 'free competition' from unjustified obstacles through a selective approach to access to patents (and techno-copyright²⁰) protection. So it shares the same objective of the evoked trends to discourage 'poor quality' patents, in line with the philosophy of, i.a., the quoted *KRS Int'v. Teleflex* decision .

May I emphasize, in concluding my reflection, that the risk of an inflation of unjustified obstacles to competition is even more evident, and serious, in relation to 'technology copyright', i.e. the copyright protection of software. This, because of the low level of 'creativity' traditionally required to access copyright protection. Now, such low level was, and is justified, in the name of freedom of expression, with respect to 'traditional' copyrightable works: artistic and scientific ones, i.e. works of merely intellectual, non- utilitarian, fruition— indefinitely variable in the expressive profile , hence posing no problem of 'monopolization' .

But software - despite its fictitious assimilation(first in the US, then in Europe) to 'literary works' - is just and totally technology: it is indeed 'the' technology of our age. So, in order to receive exclusive protection, its 'creativity' should be assessed with the same rigor that the US SC, in *KRS*, demanded for patents.

A point for future reform.
G.G.

¹⁹ 'Doctor' Dulcamara ('Dolce e amaro', sweet and sour) is a comic character of Gaetano Donizetti's opera 'L'elisir d'amore'. He is a Venetian charlatan that administers fake medicaments.

²⁰ I refer to the copyright protection of computer programs ---- 'the' technological instrument of contemporary knowledge economy—introduced upon the initiative of a *National Commission on New Technological Uses of Copyrighted Works (CONTU)*, instituted under the first Clinton Administration, composed by representatives of the major IT industries, and orchestrated by a

célèbre Washington lobbyist, Bruce Lehman. The US legislator promptly followed suit with the 1980 Software Copyright Act ; so did, ten years later, the European [Directive 91/250 EC, now 2009/24 EC. That ascription was nevertheless not accepted by/ within the Berne Convention, due to the opposition of many Developing Countries , worried of an incoming ' ITC neocolonialism']. That historical expansion beyond the classical boundaries of the area of 'literary[including scientific] and artistic works' – also supported by the fictitious assimilation of computer programs to 'literary works' [see

e.g. *Apple Computer Inc. v. Franklin Computer Corp.*, 714 F.2d 1240[3rd Circ. 1983]-- granted a true bonanza esp. for big first movers of the software industry, who could enjoy a type of protection that—compared with that of patents—features substantially no cost and no tests of access, a 'huge' term of duration, no subjection to compulsory licenses, no green light for follow-on competitors even for the mere elaboration (not just the commerce, as for patents) of derivative improvements.



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