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**PATENTABILITY UNDER TRIPS:
THE NEED FOR UNIFORMITY**

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ABSTRACT

International intellectual property law has never been uncontroversial, and patent law in particular has been the subject of heated debate. The advent of TRIPS seems to have fuelled rather than ended these discussions, as arguments continue to rage on in developing countries about the subject-matter and patent term provisions of TRIPS and the ways in which developed countries have purportedly used TRIPS to impose their own laws on the world. However, such an approach misses the point of TRIPS altogether: the need for international harmonisation. By examining two recent examples from US case law, it becomes apparent that the developed nations need harmonisation as much as the developing nations do, and thus the focus should be on facilitating full harmonisation rather than impeding it through challenging specific provisions.

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I. THE GENESIS OF THE TRIPS AGREEMENT

The adoption of the TRIPS Agreement¹ in 1995 was a unique development in international intellectual property law. The agreement mandated minimum standards that must be met by all nations with regard to the protection of intellectual property. “All nations” meant all nations that participate in the World Trade Organisation (WTO) and, from a practical perspective of trade policy and economics that meant, truly, *all* nations. The TRIPS Agreement became the global Constitution of intellectual property law. Under it, *all* nations must ensure that their domestic laws conform to the TRIPS standards, or risk sanctions under the WTO system.

No area of intellectual property law has been quite as controversial as patent law. The TRIPS Agreement contains two specific provisions directed towards raising standards for countries that were deemed by developed countries to fall short of a “minimum” level. The countries advocating these two provisions were primarily the United States and, secondarily, Japan and countries in Europe. The two specific provisions concerned the scope of patentable subject matter and the term (i.e. length) of patent protection. Thus, Article 27(1) provides that “patents shall be available... without discrimination as to...the field of technology...”² and Article 33 states, “The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”³ These two provisions were of great interest to developed countries, which advocated minimum standards, and of great concern to countries such as India and Brazil, which viewed such standards as improper interference in domestic policy.

II. IS THERE A DEBATE ON PATENTABILITY?

Lost in the debate over these two provisions – subject-matter coverage and patent terms – was a serious consideration of other important aspects of patent law. Article 27 of TRIPS effectively codified the alternative substantive standards of patentability derived from United States patent law and the European Patent Convention. The standards of patentability in the European Patent Convention reflect Japanese law. Thus, Article 27(1) provides that inventions are patentable if they are “new, involve an inventive step and are capable of industrial application.”⁴ The phrases “inventive

¹ Agreement on Trade-Related Aspects of International Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

² *Id.* at art. 27(1).

³ *Id.* at art. 33.

⁴ *Id.* at art. 27(1).

step” and “capable of industrial application” track the European Patent Convention standards. To accommodate the United States’ “non-obviousness” and “utility” requirements, the footnote to Article 27(1) states: “For the purposes of this Article, the terms ‘inventive step’ and ‘capable of industrial application’ may be deemed by a Member to be synonymous with the terms ‘non obvious’ and ‘useful’ respectively.” Similarly, to accommodate United States law on disclosure requirements, Article 29(1) provides that “[m]embers shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.”⁵ Giving leeway to the unique United States “best mode” requirement, Article 29(1) goes on to provide, generously, that a member (that is, a WTO country) “may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.”⁶

The TRIPS Agreement thus incorporates standards of patentability as applied in the United States and Europe internally for the purposes of their own laws. Notwithstanding this bias, and an ostensible disregard for the patent laws of any other countries, the requirements of patentability, subject matter coverage including coverage of pharmaceutical products, and the term of protection (twenty years from patent filing) have received universal acceptance. I believe that discussions about those fundamental issues should be deemed closed and all WTO members should comply, fully and in good faith, with these standards.

III. PATENTABILITY AND THE INTERPRETATION OF CLAIMS: A STORY OF INCONSISTENT STANDARDS

However, other important questions about patent protection standards can and should be considered open and subject to debate at the national level and also, perhaps, at a transnational level. These issues include basic questions on patentability, such as what constitutes an unobvious advance over the prior art, and what constitutes a sufficient disclosure of a broadly claimed invention. There are conflicting approaches to treating patent claims in different jurisdictions; some states may allow a broadly claimed invention as an enabling disclosure, while other states have disclosure requirements that place a more onerous burden upon the inventor. Similarly, there are no uniform rules that are applied to the interpretation of patent claims and their scope.

⁵ *Id.* at art. 29(1).

⁶ *Id.*

Below, I will give specific examples derived from case law in the United States illustrating the importance of having consistency in these standards. But consider in the abstract the following:

Pharmaceutical company X files an application claiming a therapeutically valuable new chemical entity (NCE). It obtains a patent (let us assume patents in all significant markets) claiming the chemical entity. The company X does further research and determines that a compositional structure makes the administration of the NCE better, on a weekly dosage rather than a twice daily dosage. It files subsequent applications for the improved usage of the NCE. Company X launches its commercial drug, using both the new chemical entity and the improved compositional structure. Upon expiration of the primary patent, which claims the new chemical entity, questions arise as to the secondary patent, which may be described as an “improvement” or “derivative”. The second patent, if upheld, effectively extends Company X’s exclusive rights over its commercial product, thereby precluding generic equivalents. Is the new compositional structure patentable? Is it new and “non-obvious” in view of the prior art, which includes the new chemical entity? Does it meet the TRIPS “inventive step” standard? Further, assume that a potential generic competitor proposes to market a composition that is not identical to that claimed in the second patent but that is, arguably, “equivalent”. Does the composition infringe the second patent? These are difficult issues, ones with significant economic implications, and the TRIPS Agreement provides no guidance on these.

If one looks to jurisprudence in the United States, Europe and Japan, the primary sources of the TRIPS patentability standards, one will find a variety of opinion. Indeed, the standard of patentability has ebbed and flowed over time. TRIPS took the enormously important step of creating global standards for patent protection. It should follow that all members of the global community may participate in the articulation and refinement of the standards, including, most particularly, the “inventive step” standard for patentability. Legislative bodies, patent granting agencies, courts, scholars, and commentators in all member countries may address, in good faith, what the core standards of patent law mean. Evolution of uniform standards on patents will confer a practical advantage; inventors and innovators around the world may obtain a property right of consistent scope in all countries, that is, in the global economy.

The essential point is that the details of articulating and applying patent law standards are as important as the postulation of standards in the abstract. I set forth below two specific case law examples.

A. Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.

An exemplary recent decision pertaining to pharmaceutical patent protection is *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*,⁷ in which the Court of Appeals for the Federal Circuit affirmed a district court's preliminary injunction that removed from the market a generic competitor's product. The patent owner was the large pharmaceutical firm Pfizer; the generic competitor was Ranbaxy, a large Indian drug manufacturer. The drug was an "angiotensin converting enzyme (ACE) inhibitor". The patent claimed a particular metal stabilizer and a "saccharide" added to the primary ACE inhibitor to minimise cyclisation, hydrolysis and discolouration. To gain a sense of the economic dimensions of such cases, one should consider first that this particular case only deals with a preliminary injunction (a court order pending a complete trial) and that, to meet the legal requirement for obtaining such an extraordinary order, the plaintiff (the patent owner Pfizer) was required to post a cash bond to the tune of US \$200,000,000.

A key issue in the case, as in so many patent cases, was the proper interpretation of the patent's claim language. The claim required a "saccharide". The accused infringer's drug included a microcrystalline cellulose, which is a polysaccharide but not a sugar. The accused infringer argued that "saccharide" was limited to "sugars" and, therefore, it did not infringe the patent's claims. The Federal Circuit affirmed the district court's tentative decision that "saccharide" was not limited to sugar. It did so despite significant support in the patent itself for a contrary conclusion. The patent referred to "saccharides (i.e., sugars)". In common English language usage, the phrase "i.e." constitutes a definition, meaning "in other words. . ." and is derived from the Latin phrase "id est". However, the court relied on other language in the patent to reach a contrary conclusion. This may seem to some a rather particular point of linguistic technicality, but consider how much was at stake, not only for the generic manufacturer (Ranbaxy) but also for consumers who must continue to pay a high price for the patented drug.

Implicit in the court's decision are standards regarding how to interpret patent claim language and assess patent claim scope. These are important standards that any patent system must evaluate and assimilate. At stake are policies, such as the need for clarity and clear notice to potential competitors and the need to provide an appropriate scope of protection for innovators. How to balance these policies should be the subject of rigorous discussion and, hopefully, consensus among members of a globalised patent law regime.

⁷ 395 F.3d 1324 (Fed. cir. 2005).

B. Merck & Co. v. Teva Pharmaceuticals USA, Inc.

A second example, again a recent case dealing with pharmaceuticals, will, probably, perplex a reader not familiar with the vagaries of case law on patents in the United States, because it seems so inconsistent in tone with the prior example.

At issue in this case, *Merck & Co, v. Teva Pharmaceuticals USA, Inc.*,⁸ was a patent that claimed a method of treating and preventing osteoporosis through less than daily administration of bisphosphonate compounds, specifically alendronate monosodium trihydrate. The basic (new) chemical entity, that is, part of the prior art, was known and its administration on a daily dosage basis was also known. Hence, the patent was based on a change from daily administration (with a small dosage) to a weekly dosage (with a larger dosage, “about 70 mg” and “about 35 mg”). Common sense would suggest that such a change would have been “obvious”. Yet the patent owner relied on evidence that a larger dosage would cause adverse effects in patients. To counter that showing, an accused infringer relied on two newsletter publications that suggested weekly dosages (40 mg and 80 mg). The Federal Circuit found the patent not valid on grounds of obviousness.

First, the Federal Circuit addressed an issue of claim interpretation. The issue should be as perplexing as that of the prior case on “i.e”. In this case, the key word was “about”, a word that patent professionals commonly use to give added scope to a limiting word or phrase. To reiterate, in this patent, the claims required, *inter alia*, administering once weekly “about 70 mg” and “about 35 mg”. Typically, patent owners urge a broad construction to disputed claim language, the purpose being to establish infringement. Here, however, the patent owner argued for a very limited construction, the purpose being to distinguish the prior art newsletters’ disclosure of 40 mg and 70 mg. In what must seem an odd argument, the patent owner argued that the claims meant *exactly* 70 mg and 35 mg despite the word “about”. The trial court agreed, based on the language in the patent. The Federal Circuit, however, disagreed, interpreting “about” in its ordinary parlance, and construing that it should mean *approximately* 70 mg or 35 mg. Secondly, the Federal Circuit addressed the basic patentability standard of obviousness, and held that the claims were invalid because their subject matter would have been obvious to a person of ordinary skill in the art in view of the two prior art newsletters.

However, what is important for our consideration is the manner in which, in both these cases, the interpretation of claims was addressed. In *Pfizer*, the attempt of the patent holder was to interpret “saccharide” in the broadest possible manner,

⁸ 395 F.3d 1364 (Fed. Cir. 2005).

despite the presence of the term “i.e.” in the claim itself, qualifying the former term to mean “sugar”. In the *Merck* judgment, the term “about” was given a strict interpretation, thus rendering a commercially successful patent void. What needs to be underscored here is that these two cases demonstrate that there exist no uniform standards to interpret patent claims. This is the need of the hour, for in the absence of any such uniform standards, the patentability requirements of TRIPS, as well as its attempt to globalise standards, may be rendered nugatory.

IV. CONCLUSION

Therefore, while prior discussions on patent law have focused on a limited set of issues, such as subject matter coverage and patent term, these issues are effectively settled by TRIPS, and the nature of the origin of these standards should no longer be considered relevant to current TRIPS-related discussions. It is time to focus on more pressing and current issues, such as the interpretation of patent claim scope. However, as long as inconsistencies persist between courts in matters such as the interpretation of patent claims, it is difficult to claim that *any* sort of “minimum standard” can be said to exist on a global scale, and the cases above illustrate how such inconsistencies may occur even *within* a country, thus impeding the evolution of a consistent patent jurisprudence upon which one can rely when filing claims. In theory and in practice, it is thus imperative that, for TRIPS to be truly effective, there must be a uniformly accepted set of principles for the interpretation of claims and patent scope.