Novartis v Union of India and the Person Skilled in the Art: A Missed Opportunity

Sivaramjani Thambisetty

LSE Law, Society and Economy Working Papers 2/2014
London School of Economics and Political Science
Law Department

Novartis v Union of India and the Person Skilled in the Art: A Missed Opportunity

Sivaramjani Thambisetty*

Abstract: The Indian Supreme Court's (SC) decision in *Novartis v Union of India* (*UOI*), decided earlier this year, formalizes a concerted and focused attempt by Indian law-makers to reject trivial secondary pharmaceutical inventions. The SC concluded that S 3(d) of the Indian Patents Act made new forms of known substances ineligible for patents in the absence of 'enhanced efficacy', which in this case was defined as 'therapeutic efficacy'.

This paper argues that the SC wrongly ignored the context of S 3 and Chapter II of the Act, which is a medley of exclusions, exceptions and ineligible subject matter, each of which can be differentiated by the need to involve the person skilled in the art standard. In this case a greater appreciation of the flexibility afforded by this notional standard as part of a broader non-obviousness enquiry would have led the SC to a more conventional and legitimate legal option. Instead the SC's adoption of the patent eligibility route has paradoxically left it much less room to manoeuver the law around secondary pharmaceutical inventions.

Keywords: S 3(d), pharmaceutical patents, efficacy, person skilled in the art, invention, patentable invention.

---

* Lecturer in Intellectual Property Law, Law Department, London School of Economics and Political Science. A version of this paper will be published in the *Queen Mary Journal of Intellectual Property*, forthcoming January 2014.

1. INTRODUCTION

On 1 April 2013, the Indian Supreme Court handed down an eagerly awaited decision in *Novartis v UOI*.[1] In the few months since the decision was handed down, it has generated a great deal of interest online, commentary and even political backlash. On the one hand the decision directly contributed to India being placed on a trade blacklist by the United States, due to the serious concerns raised by the 'innovation climate in India' that 'risks hindering the country's progress towards an innovation-focused economy'.[2] On the other hand, Médecins Sans Frontières called the litigation an 'attack on the pharmacy of the developing world'. Additionally, 170 members of the US Congress have written to President Obama citing a pattern of 'inappropriate revocation' of patents on several life-saving drugs. The letter claims that several other imminent decisions relating to compulsory licences are being 'improperly driven by an interest in growing the pharmaceutical market in India'.[3]

Preceding this case there have been reasoned calls from academics for a more functional approach to TRIPS flexibilities,[4] criticism of dispute settlement decisions at the WTO that have consistently underplayed the larger picture of which IP rights are a part,[5] analysis of the history, background and possibilities presented by S 3(d) of the Indian Patents Act, 1970[6] and claims that S 3(d) is not a radical departure from approaches taken by developed countries to limit patentability of secondary pharmaceutical innovations.[7] Empirical analysis shows that S 3(d) currently appears to be playing a surprisingly small role in the rejection of patent applications in India.[8] A legally unrelated decision in *Bayer v Natco*,[9] in

---

[1] *Novartis v Union of India* on 1 April 2013 www.indiankanoon.org/doc/165776436/ accessed 2 September 2013.

[2] 2013 Special USTR 301 Report 38. www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf accessed 2 September 2013.

[3] Full text of the letter is available at http://keionline.org/sites/default/files/06-18-13-House-India-Letter_1.pdf accessed 2 September 2013.

[4] R Dreyfuss 'TRIPS and Essential Medicines: Must One Size Fit All? Making the WTO Responsive to the Global Health Crisis' in T Pogge and others (eds), *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge University Press 2010).

[5] DB Barbosa, M Chon and A Moncaya Von Hase, 'Slouching Towards Development in International Intellectual Property Law' (2007) *Michigan State Law Review* 71.

[6] S Basheer and P Reddy, 'The 'Efficacy of Indian Patent law: Ironing out the Creases in Section 3(d)' (2008) *SCRIPTed* 5(2). S 3(d) states: the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

[7] L Lee 'Trials and TRIPS-ulations: Indian Patent law and Novartis Ag v Union of India' (2008) *Berkeley Technology Law Journal* 281.

[8] B Sampat, K Shadlen and T Amin, 'Challenges to India's Pharmaceutical Patent Laws' (2012) *Science* 337 (6093) 414–415

which the Indian Intellectual Property Appellate Board (IPAB) upheld the first compulsory licence for a pharmaceutical in India, has also added to the clamour.[10]

Placing *Novartis v UOI* against a backdrop of patent law in the UK and in Europe highlights the international legal significance of this decision. The UK experience of patent protection and enforcement has largely been positive for pharmaceutical companies who appear to consider this forum as fair and even friendly.[11] Although there are many aspects of Indian patent law that are directly resonant of UK patent law, higher appellate courts in India, rather confusingly, rely on material from a wide array of jurisdictions. My aim here is to draw on the depth of categorical sense and clarity maintained by judicial decisions in UK law to make a number of observations around the use of the person skilled in the art and the distinction between patent eligibility and patentability criteria that could be relevant to Indian patent law going forward. These are by no means comprehensive of all the legal and political implications of *Novartis v UOI*.

The central issue here is whether S 3(d) is a question of patent eligibility or a heightened standard of non-obviousness for pharmaceutical and chemical substances.[12] In either case there appears to be broad agreement that S 3(d) is a ground for rejection of derivative or secondary pharmaceutical inventions. If it is a supplementary ground for rejection of such inventions then the question of incompatibility with TRIPS arises. Others have taken the position that S 3(d) is not very different from fragmented patentability standards that in effect require a closer scrutiny of derivative or secondary chemical and pharmaceutical inventions.[13]

Does *Novartis v UOI* really set up an atypical and anomalous response to secondary pharmaceutical inventions? And what might the decision mean for the general approach to patent-eligible subject matter in India and elsewhere? The jurisprudence around the interpretation of S 1 of the UK Patents Act, although not as clear as many commentators would like, nonetheless provides a useful

---

[9] Order of the IPAB OA/35/2012/PT/MUM www.ipabindia.in/orders.aspx accessed 2 September 2013.

[10] S Thambisetty, 'Compulsory Licenses for Pharmaceuticals: An Inconvenient Truth' LSE@India 25 March 2013. http://blogs.lse.ac.uk/indiaatlse/2013/03/25/compulsory-licenses-for-pharmaceuticals/ accessed 2 September 2013.

[11] This view may be justified by the distribution of matter in the European Patents Court where chemical and pharmaceutical cases are to be litigated in London. Currently 32 per cent of all UK patent litigation is conducted by chemical and pharmaceutical firms and 60 per cent of all litigants in all sectors comprise large firms. C Helmers and L McDonagh, 'Patent Litigation in the UK' (2012) 12 LSE Law, Economy and Society Working Paper Series 15/2012 www.lse.ac.uk/collections/law/wps/WPS2012-12_Mcdonagh.pdf accessed 2 September 2013.

[12] As held by the Indian IPAB; see S Raghavan, 'The Patent Failure of Novartis with Gleevec' 4 works.bepress.com/cgi/viewcontent.cgi?article=1309&context=srividhya_ragavan accessed 2 September 2013. A related decision from the Madras High court rested on the constitutionality of S 3(d) where the court ruled that the provision was constitutional but that it did not have the jurisdiction to rule on the TRIPS Agreement. For an analysis of the Madras High Court decision see S Basheer, 'The "Glivec" Patent Saga: A 3-D Perspective on Indian Patent Policy and TRIPS Compliance' www.atrip.org/Content/Essays/Shamnad%20Basheer%20Glivec%20Patent%20Saga.doc accessed 2 September 2013.

[13] S Raghavan, ibid. Such as the scrutiny in *Pfizer v Apotex*, 480 F 3d 1348 (Fed Cir 2007) where a pharmaceutical salt form of a known substance, providing greater solubility and stability, was held to fail the inventive step test.

vocabulary to compare and contrast the approach of the Indian Patents Act to 'inventions that are not patentable' in S 3, India Patent Act. A proper characterization of S 3(d) is essential to either rejecting or accepting its status as a legal outlier in terms of TRIPS obligations. Unfortunately the SC's reasoning here fell short of fully explicatory, and may even have damaged the functionality in S 3(d) to provide a robust basis for the rejection of trivial patents on secondary pharmaceutical innovation by ignoring the role of the person skilled in the art in S 3(d).

2. THE NOVARTIS REJECTION IN INDIA

Novartis v UOI has been working its way through Indian courts since 2006, and Basheer and Reddy provide a careful analytical rendering of all relevant legal decisions up until the current case at the Supreme Court.[14] The Novartis patent application (also referred to as the Zimmerman patent in the decision) was first rejected in 2005,[15] for lacking novelty as well as on grounds of not meeting the 'efficacy' requirement in S 3(d).

The original patent for Imatinib in free base form (the Zimmerman patent) was granted in the US in 1993.[16] The application that was rejected in India was for Imatinib Mesylate, specifically the beta crystalline form, a salt of the free base disclosed in 1993. The Indian patent in question for Imatinib Mesylate in beta crystalline form (hereafter IMBCF) was filed in 1998 and claimed that the beta crystalline form was a new product because of new and superior properties, such as a better beneficial flow, better thermodynamic stability and lower hygroscopicity. These properties allegedly allowed, among other uses, for better processing and storage.[17]

The *Novartis* application claimed that by starting with Imatinib in free base form, they produced Imatinib Mesylate, and then produced the beta crystalline form of the salt Imatinib. In pharmaceutical chemistry, a different crystalline form of the same chemical substance is called a polymorph. The application compares the beta crystalline form with the free base Imatinib to say that 'all the indicated inhibitory and pharmacological effects are also found with the free base'. It is worth noting that the reason why the otherwise widely granted Zimmerman patent on Imatinib does not exist in India is to do with timing rather than any

[14] S Basheer and TP Reddy (n 6). Also see S Raghavan ibid.
[15] *Novartis AG v Natco Pharma and Others,* Indian Patent Office, Application No.1602/NAS/1998 (25 January 2005) http://lists.essential.org/pipermail/ip-health/2006-March/009200.html accessed 2 September 2013.
[16] US patent number 5,521,184.
[17] The specification of the patent application as filed in India is available at www.scribd.com/doc/88234320/complete-specification accessed 2 September 2013.

patentability requirements. At the time India was not granting patents on pharmaceutical products, and when it started granting them in 2005, it only had to accept applications going as far back as 1995.[18]

The patent office rejection[19] cites disclosure in the 1993 patent, which discloses methanosulphonic acid as one of the salt-forming groups, and where acid addition salts are produced in a conventional manner. The rejection is not exhaustively reasoned but appears to explain the decision on the basis of a limited number of conventional salts, making the disclosure of Imatinib Mesylate implicit in the disclosure of the free base, Imatinib. In other words and in essence, the novelty of the crystalline form of Imatinib Mesylate is impugned by an implicit disclosure in the application for the free base, Imatinib. However, this finding was not condoned by the Supreme Court, which found that although Imatinib Mesylate (non-crystalline form) itself was inherent in the teaching of Imatinib in the Zimmerman patent, the same could not be said for the beta crystalline form of Imatinib Mesylate, which required an 'additional manipulative step' in order to produce it.[20]

The finding by the SC that the beta crystalline form was new in the sense that it was not known from the Zimmerman patent, is a critical juncture in its decision for two reasons. First it immediately denotes the point of comparison with the immediately preceding relevant 'known substance' as a consequence of the wording of S 3(d). IMBCF is the 'new form' of a 'known substance' and any reference to evidence of enhanced efficacy will have to be made in relation to Novartis' earlier invention, Imatinib Mesylate (non-crystalline form).

Unfortunately for Novartis, all their evidence on bioavailability compared IMBCF to Imatinib in free base form while physico-chemical properties were compared to the alpha crystalline form of Imatinib Mesylate. Given that the latter was rejected as being irrelevant, the lack of data showing increased efficacy of the beta crystalline form of Imatinib Mesylate over the non-crystalline form of Imatinib Mesylate turned out to be the basis of the upholding of the rejection of Novartis' patent.[21]

Secondly, once this substance was accepted as new, a related query would have been whether it was also inventive, given the disclosure of Imatinib Mesylate. However, the SC quickly veered off into a 'patent eligibility' enquiry rather than asking whether this substance was inventive:

---

[18] When the transitional mail-box facility began in India, Novartis filed an application in 1996 and the application was reviewed in India after 2005. 'If Glivec had been invented a few years later, however, it would most likely be protected in India. These details are important for two reasons. First, they indicate that, for all the hoopla, Glivec is more a victim of timing than of Section 3(d). Second, this suggests that just as Glivec would likely be patented were it invented two years later, new drugs based on new molecules are patentable and are being patented in India.' See K Shadlen, 'Learning from India? A New Approach to Secondary Pharmaceutical Patents' http://blogs.lse.ac.uk/indiaatlse/2013/05/03/a-new-approach-to-pharmaceutical-patents/ accessed 2 September 2013.

[19] n 16.

[20] *Novartis* [124], citing with approval the finding of the US Board of Patents Appeal on the limits of the teaching in the Zimmerman patent.

[21] *Novartis* [165] – [168].

> This leaves us with the beta crystal form of Imatinib Mesylate, which, for the sake of argument, may be accepted to be new, in the sense that it is not known from the Zimmermann patent. (*Whether or not it involves an 'inventive step' is another matter, and there is no need to go into that aspect of the matter now*). The beta crystalline form of Imatinib Mesylate being a pharmaceutical substance and moreover a polymorph of Imatinib Mesylate, it directly runs into section 3(d) of the Act with the explanation appended to the provision [emphasis added].[22]

This turn away from inventive step towards patent eligibility bucks the trend. In UK case law, largely driven by EPO decisions, we have seen a distinct shift away from patent eligibility that poses difficult questions of policy towards the more instrumental rationality of patentability criteria.[23] In the context of gene patents, Pila observes a shift towards industrial application,[24] while early on in 1990 Sherman noted the preoccupation with how biotechnological inventions came into being expressed through the criterion of non-obviousness, rather than whether they are patentable in the first instance.[25]

Whatever the broader merits or demerits of such a shift, in *Novartis v UOI* the move towards a patent eligibility enquiry rather than an inventive step approach does no favours to the Indian legal position on secondary pharmaceutical inventions, as it presents treacherous legal terrain attracting unwelcome international political attention, when there is a relatively uncomplicated method of assessing whether a patent ought to be granted here.

3. THE IMPORT OF S 3(D)

The central enquiry underpinning the decision in *Novartis* is the true import of S 3(d) of the Indian Patents Act and its relationship with clauses 2 (1)(j) (defines

---

[22] *Novartis* [158].

[23] This shift is charted in S Thambisetty, 'Learning Needs of the Patent System: Implications from Institutionalism for Emerging Technologies like Synthetic Biology' (2013) LSE Law, Society and Economy Working Paper Series No. 18/2013 www.lse.ac.uk/collections/law/wps/WPS2013-18_thambisetty.pdf accessed 2 September 2013. Also see examples noted in n 59.

[24] '[Third], I reject the premise of much contemporary law and jurisprudence that the European patent system exists – and ought to exist – for the purpose of advancing the practical arts, with the result that if a subject matter is novel, inventive and useful, it is a subject matter that ought to be patentable. Instead, I suggest that the purpose of the system ought to be linked to advancing the industrial arts, and conceptions of inherent patentability limited accordingly.' in Pila, 'The Future of the Requirement for an Invention Requirement: Inherent Patentability as a pre and post Patent Determinant' (2010) Oxford Legal Studies Research Paper No. 35 4.

[25] B Sherman, 'Patent Law in a Time of Change: Nonobviousness and Biotechnology' (1990) *Oxford Journal of Legal Studies* 278.

'invention' as being new, inventive and industrially applicable) and (1)(ja) (defines 'inventive step') of S 2(1). The enquiry can potentially be broken down into two stages – Is IMBCF novel, inventive and industrially applicable? If yes, it satisfies S 2(1)(j) and qualifies as an 'invention'. Secondly, can a qualifying 'invention' be denied patentability on grounds of being an 'invention that is not patentable' in S 3? In the decision, having first identified the beta crystalline form of Imatinib Mesylate as a new form of a known substance, the Supreme Court proceeded directly to S 3(d), not as one aspect of the 'invention' enquiry under S 2(1)(j) but as part of a patent eligibility enquiry (or 'patentability' as it is referred to in the decision).[26]

Based on the language in S 2(1)(j) and S 3(d) it seems open to the SC to consider the non-obviousness of the beta crystalline form of Imatinib Mesylate in order to assess whether it was indeed an 'invention'. Only if it fulfils novelty, inventive step and industrial application can it qualify as an 'invention'. S 3(d), I submit, should normally only kick in once the subject matter in question qualifies as an 'invention' or as part of the 'invention' enquiry; for S 3 as a whole refers to '*inventions* that are not patentable' (emphasis added). The advantage of sticking with the definition of invention first would be to undertake an inventive step analysis as part of which the explanation of S 3(d) can be better used. The failure to address the non-obviousness of IMBCF is a misstep in the logic of the SC and represents a missed opportunity to maintain the full functionality of S 3(d)[27] while steering clear of any doubt over TRIPS compatibility.[28]

Moreover, S 3(d), I submit, is unsuitable for a patent eligibility enquiry due to the heavy and necessary involvement of the person skilled in the art standard, rather than a legal principle that a judge can pronounce on without necessary access to factual evidence specific to the claims of that patent application. Whether law and fact should be treated as two distinct categories, or categories where one 'bleeds' into the other in patent law (for instance where law has to be applied to the facts), is one part of a much larger debate in jurisprudence.[29] In patent law facts are of crucial significance for validity and claim scope –

---

[26] The Indian decision inverts the terminology as it is used in the UK and Europe where 'invention' requirement is the inherent patentability enquiry as opposed to the patentability enquiry that includes novelty, inventive step and industrial application.

[27] Prof S Basheer, academic-intervenor in the case, cautioned the court over the potential implications under TRIPS of failing to bridge the gap between inventive step and patent eligibility. Opinion available at www.spicyip.com/docs/petition-tenth-pdf.pdf accessed 2 September 2013.

[28] The TRIPS agreement requires patents to be granted for all fields of technology. An additional hurdle for chemical and pharmaceutical patents alone is potentially discriminatory and runs the risk of being incompatible with Art 27 of the TRIPS Agreement. The SC concluded that 'We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.' *Novartis* [103].

[29] A Rai, 'Engaging Facts and Policy: A Multi-Institution Approach to Patent System Reform' (2003) *Columbia Law Review* 1035.

conventionally they are either irrelevant or less relevant[30] when considering aspects of patent eligibility or exclusions. So S 3(d) as a patent eligibility question also implies an unusual approach to a legal determination here.[31] The operative aspects of S 3(d) are in effect an exception to an exception – where enhancement of known efficacy overrides the explicit exclusion of new forms of known substances.

Here the court relied on the generic meaning of 'efficacy' to note that

> Efficacy means 'the ability to produce a desired or intended result'. Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be 'therapeutic efficacy'. The question then arises, what would be the parameter of therapeutic efficacy and what are the advantages and benefits that may be taken into account for determining the enhancement of therapeutic efficacy?[32]

Having decided that S 3(d) applied in the field of 'chemical substance, especially medicine' the court ought to draw on the content of 'efficacy' as understood by the person skilled in the field. Instead, the court concluded, apparently as a matter of legal precept that:

---

[30] J Pila makes a strong case for the patent eligibility question to 'leak' into questions of patent validity, which, if accepted, going forward could lead to more fuzzy determinations of eligibility in UK and European law. See J Pila, 'The Future of the Requirement for an Invention: Inherent Patentability as a Pre- and Post- Patent Determinant' in G Ghiddini and E Arrezo (eds), *Biotechnology and Software Patent Law: A Comparative Review on New Developments* (Edward Elgar 2011) 55-90. Also see J Pila, 'Patent Eligibility and Scope Revisited in Light of Schutz v Werit, European Law and Copyright Jurisprudence' in RC Dreyfuss and JC Ginsburg (eds), *Intellectual Property at the Edge: The Contested Contours of IP* (Cambridge University Press 2013) preprint available at http://users.ox.ac.uk/~lawf0169/pdfs/pila_patenteligibilityandscoperevisited.pdf accessed 2 September 2013.

[31] As a matter of academic debate Sichelman makes an argument for 'patent eligibility scope' where patent eligibility is set at a low threshold, following which judicial construction of patent claims would weigh the costs of foreclosing use of the invention against benefits of its disclosure. See T Sichelman, 'Funk Forward' in RC Dreyfuss and JC Ginsburg (eds), *Intellectual Property at the Edge: The Contested Contours of IP* (Cambridge University Press 2013) Available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2035027 accessed 2 September 2013. Pila notes that such an approach would currently run counter to the grain of UK patent law. J Pila, 'Patent Eligibility and Scope Revisited' ibid (n 33).

[32] *Novartis* [180].

> What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, [as seen above], is its therapeutic efficacy.[33]

Rather than assessing the content of 'efficacy' from the viewpoint of the person skilled in the relevant art, the court took the view of two legal experts on the meaning of 'efficacy' and the factors that may be used under it.[34] The SC concluded that it did not have to pronounce on all aspects of 'efficacy' that may be used under S 3(d), but nonetheless felt comfortable limiting 'efficacy' to 'therapeutic efficacy'. This incomplete reasoning is not just inexpedient, it is also illogical as it limits the meaning of 'efficacy' without a full enquiry or without clarifying methodology that may be used in future to clarify the content of this term. The court's conclusion here is essentially a direct consequence of the non-use of the notional standard of 'person skilled in the art' as a result of which the court's view that S 3(d) is an eligibility question rather than a patentability criterion naturally follows.

3.1 Patentable Invention v 'Invention' and 'Inventions that are not Patentable'

It would be useful here to pause to compare and contrast the enquiry in *Novartis* with the discussion of 'invention' in *Biogen v Medeva*[35] in UK law. The Indian act does not use the term 'patentable invention' in any definitional sense,[36] and there is no sense in which 'invention' implies 'patentability'. It is apparent from a reading of S 2(1)(j) and S 3 together that 'inventions' are novel, inventive and industrially applicable; and not all 'inventions' are patentable.

In contrast, the UK Patent Act uses the term 'patentable invention' in S 1 where it is defined as new, inventive and industrially applicable and not specifically excluded.[37] The term 'patentable invention' gives rise to the question whether 'invention' has to be defined separately from the positive characteristics of novelty, inventiveness and industrial applicability. The margin for doubt exists primarily due to the use of the joint term 'patentable invention' – suggesting that the unspecified term 'invention' is a larger category than mere 'patentable inventions'. Indeed, it suggests, as observed by the House of Lords (HL) in *Biogen v Medeva*, that logically perhaps one should first decide whether the claimed invention can properly be described as an invention at all. The HL here famously decided that in most cases there would be no need to a priori define 'invention' separately from 'new', 'inventive' and 'industrially applicable'.[38]

---

[33] Ibid.
[34] (n 27). The opinion of Prof S Basheer as an academic-intervenor in the case is available at www.spicyip.com/docs/petition-tenth-pdf.pdf accessed 2 September 2013.
[35] *Biogen v Medeva* [1996] UKHL 18.
[36] The term is used once in S 157A to do with the security of India.
[37] S 1, UK Patents Act 1977 reflects Art 52 of the European Patent Convention 1973 (EPC).
[38] *Biogen v Medeva* [42]–[46].

The Indian iteration of the law cuts through this cognitive underpass by keeping 'invention' and 'patentable' severable. While UK decisions have bemoaned the impossibility of exhaustively defining 'inventions', Indian law has taken the approach of attempting to define 'what are not inventions'. Instead of implying the need for a precursory definition of 'invention', the Act goes on to define 'inventions that are not patentable' – thus leaving no room for doubt that 'inventions' – even those that are new, inventive and industrially applicable, are a bigger category than those eligible for patents.

As the SC observed:

> We have seen the meaning of 'invention'; we have also seen earlier that the Patents Act, 1970, dealt with 'invention' and 'patentability' as two distinctly separate concepts. The duality of the two concepts is best illustrated by section 4 of the Act, which prohibits the grant of patent (either process or product) 'in respect of inventions relating to atomic energy falling within sub-section (1) of section 20 of the Atomic Energy Act, 1962', and which has not undergone any change since inception. It is, therefore, fundamental that for grant of patent the subject must satisfy the twin tests of 'invention' and 'patentability'. Something may be an 'invention' as the term is generally understood and yet it may not qualify as an 'invention' for the purposes of the Act. Further, something may even qualify as an 'invention' as defined under the Act and yet may be denied patent for other larger considerations as may be stipulated in the Act.[39]

3.2 The Interpretational Context of S 3

S 3, the sole section in Chapter II, lists 16 categories of 'inventions not patentable' and is a veritable smorgasbord of subject matter[40] that includes inventions that are typically excluded (methods of medical treatment), excepted (morality) and ineligible (computer programs, mathematical methods) in other jurisdictions. It also includes S 3(a), which details subject matter that would most typically fail the industrial application requirement. S 3(b) refers to inventions the exploitation of which would be contrary to public order or morality, and there is no other provision in the Act akin to Article 53(a) of the EPC;[41] S 3(e) and (f) specifically exclude synergistic and collocation inventions, the former in the case of substances and the latter for known devices. Traditionally these are dealt with

[39] *Novartis* [91].
[40] S 3 itself prefaces the clauses with 'the following are not inventions within the meaning of this act'. This may appear to defeat the logic of my argument about deciding whether something is an invention first before embarking on a S 3 enquiry, but it makes more sense to give prominence to the chapter title here because of the diverse range of subject matter included in S 3.
[41] Reflected in S 1(3) UK PA.

under non-obviousness in UK patent law.[42] S 3(i) inter alia excludes medicinal or surgical processes for the treatment of human beings. Subsections (k) to (n) replicate article 54(2) of the EPC and S 1(2) of the UK PA but without the 'as such' clause.[43]

Because of the extent of judicial time spent on the question, largely in the context of the exclusion of computer programs, and for those steeped in UK patent law jurisprudence, it would be natural to ask whether S 3 ought to be viewed as part of the 'invention' requirement or as additional clauses that speak to patentability criteria. How important is categorical clarity between patentability and patent eligibility? In the Indian context in particular there are no clear answers because S 3 is a startlingly diverse mix of exclusions and exceptions based on policy reasons. S 3 appears to be part codified common law and part *de novo* policy and cannot as such be wholly compared with S 1(2) of the UK Patents Act.

Within this context, the wording in S 3(d) calls for a closer look:

> (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
>
> Explanation.— For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

The point made above, that the Indian SC in this case ought to have first considered whether the IMBCF is indeed an invention before considering whether S 3(d) applies, does not necessarily mean that the S 2(1)(j) enquiry has to be conducted in isolation from S 3. Indeed, several, though not all, of the S 3 clauses speak more to the definition of inventions as 'new', 'inventive' or 'industrially applicable' than patent eligibility.[44] As a direct consequence, I make the general

---

[42] In *Sabaf SpA v MFI Furniture Centres Ltd* [2005] RPC 10 [25] Lord Hoffmann refers to the EPO Examination Guidelines to state that '[…] where the claim is merely an aggregation or juxtaposition of features and not a true combination, it is enough to show that the individual features are obvious to prove that the aggregation of features does not involve an inventive step. A set of technical features is regarded as a combination of features if the functional interaction between the features achieves a combined technical effect which is different from, e.g. greater than, the sum of technical effects of the individual features'.

[43] However, the interpretation of S 3(k) is similar to UK law and EPO decisions in that the inventive step cannot lie solely in the excluded subject matter. See decision of the IPAB in *Electronic Navigation Research Institute v Comptroller General of Patents and Designs* OA/26/2009/PT/DEL www.ipab.tn.nic.in/145-2013.htm accessed 2 September 2013.

[44] In particular, clauses (f), (a), (d) and (p).

case here that an effective approach to S 3 would be to differentiate the diverse clauses in S 3 by assessing whether it calls for the involvement of the person skilled in the art. If yes, then it ought to be seen as an aspect of the enquiry in S 2(1)(j) and treated as part of the qualifying test for 'invention'. If it does not involve the person skilled in the art, then the court would be right to enquire into the patent eligibility of the invention without necessarily settling whether it was also new, inventive and industrially applicable.

Not all clauses present a straightforward choice between a factual approach based on the person skilled in the art or a substantive finding on legal principle. Take S 3(p) for instance: according to this provision an invention that is in effect traditional knowledge, or an aggregation of traditionally known components, is not patentable. This provision seems to allow for one of two possible approaches – define 'traditional knowledge' or 'traditionally known' – a task that is complicated internationally.[45] Or primarily see S 3(p) as bolstering novelty or inventive step assessment where traditional knowledge is a sub-category of prior art that anticipates an invention or influences the person skilled in the art.

Although it goes without saying that properly documented traditional knowledge can always be used as prior art, there are elements of use and recording within traditional knowledge systems that do not sit easily with the patent system. In such cases, S 3(p) can be used as counter balance to the strictly policed epistemology of knowledge in the patent system,[46] where traditional ways of 'knowing' do not impugn novelty unless that way of 'knowing' teaches or enables an invention in a manner that allows it to be worked.[47] Given the framework suggested here, clause (p) can be seen as facilitating both approaches and as presenting a judicial choice, *ex abundanti cautela*, under S 2(1)(j) or as a policy-based exclusion where the TK is ineffective in precluding a patent under generally accepted rules for non-obviousness or novelty.

The approach of using the involvement of the 'person skilled in the art' as a litmus test to clarify the interpretation of particular clauses in S 3 of the Indian Patents Act presents several advantages. It preserves the possibility of using S 3 as a vehicle for policy-based and principled rejections of particular categories of inventions, while preserving and bolstering the ability of patent offices and courts to make robust assessments of novelty and inventive step. Viewed in this way such a provision becomes a powerful legislative tool in a country that is under severe pressure to make highly visible legal decisions without a substantive body of case law to fall back upon, as is the case with chemical product patents.

---

[45] The WIPO definition acknowledges that traditional knowledge (TK) is knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity. www.wipo.int/tk/en/tk/ accessed 2 September 2013.

[46] For a general discussion see S Parthasarathy, 'Breaking the Expertise Barrier: Understanding Activist Strategies in Science and Technology Policy Domains' (2010) 37(5) *Science and Public Policy* 355–367.

[47] See G Dutfield, 'A Critical Analysis of the Debate on Traditional Knowledge, Drug Discovery and Patent–Based Biopiracy' (2011) (4) 33 *European Intellectual Property Review* 237–243.

In *Novartis*, appellants tried to claim that S 3(d) was introduced to ensure that 'discoveries' can never, by any effort at interpretation of clauses (j) and (ja) of S 2(1), be considered inventions. The SC was right to reject this reading associating S 3(d) with discoveries, but not to then conclude that S 3(d) was a patent eligibility provision. Thus:

> The submission may appear plausible if the scrutiny of the law is confined only to the Act as it stands today after undergoing the amendments in 2005. Based on the larger perspective of the development of the law of patent over the past 100 years and especially keeping in mind the debates in the Parliament preceding the 2005 amendment, it would appear completely unacceptable. We find no force in this submission that section 3(d) is a provision ex majore cautela. To our mind, the submission completely misses the vital distinction between the concepts of invention and patentability – a distinction that was at the heart of the Patents Act as it was framed in 1970, and which is reinforced by the 2005 amendment in section 3(d).[48]

Further and critically:

> We have, therefore, no doubt that the amendment/addition made in section 3(d) is meant especially to deal with chemical substances, and more particularly pharmaceutical products. The amended portion of section 3(d) clearly sets up a second tier of qualifying standards for chemical substances/pharmaceutical products in order to leave the door open for true and genuine inventions but, at the same time, to check any attempt at repetitive patenting or extension of the patent term on spurious grounds.[49]

The SC was right to focus on the substantive distinction between patent eligibility and patentability criteria – it is the difference between justifying property rights in the first place and explaining why a particular subject matter should be denied patent protection (on grounds of not being inventive or being inadequately disclosed, for instance).

However, going beyond this distinction, it is difficult to see how any court can decide on the specifics of the enhancement in efficacy without relying on evidence that is specific to a technology sector via the person skilled in the art. Without the explicit involvement of this notional standard, the observation by the court in *Novartis*, that 'efficacy' ought to mean 'therapeutic efficacy', begins to look like outright judicial policy-making that is not adequately supported by the legislative framework of patent statutes in general or even conventional legal methodology applied in patent law. These reasons add to a perception that the legal position articulated in *Novartis* is unorthodox, triggering unwelcome political

[48] *Novartis* [102].
[49] *Novartis* [103].

attention from those countries that seek to enforce a strict, or even 'TRIPS plus' standards of patentability for developing countries.[50]

In the broader context of an obviousness enquiry – the question of 'enhanced efficacy' is not of primary significance – for it will not override other concerns over how the invention was arrived at or whether it was within common general knowledge, obvious to try, or whether a surprising and unexpected result materialized. In this respect 'enhanced efficacy' can only be a subset of the broader inventive step enquiry. S 3(d) may allow the patent office and courts to narrow their enquiry to 'enhanced efficacy' first, but by no means can this be the end of the enquiry. Even if the new form of a known substance evidences enhanced efficacy, it may still fail other commonly used standards in obviousness questions. In that sense the enhanced efficacy aspect of S 3(d) is not really overly significant as a ground to deny a patent application.[51] By adopting S 3(d) first, without placing it within the context of a robust non-obviousness enquiry, the SC here has directly and, it is submitted, erroneously, contributed to this enquiry being regarded as a legal outlier.

3.3 Is S 3(d) a Legal Outlier for Secondary Pharmaceutical Inventions?

Concerns about the increasing patentability of secondary pharmaceutical inventions have grown both in UK and European patent law. If the Indian position via *Novartis* presents an oddity, it is in taking up these concerns as a matter of patent ineligibility rather than through more established non-obviousness enquiries where the person skilled in the art is called upon.

While the SC refused to consider a comprehensive definition for 'efficacy',[52] on the critical question of the relationship between bioavailability and efficacy the court decided that 'whether or not an increase in bioavailability leads to an enhancement of therapeutic efficacy in any given case must be specifically claimed and established by research data'.[53]

---

[50] See n 2.

[51] In this sense an inordinate amount of confusion has been generated by this statement of the IPAB in its decision in 2009, where it observed: 'Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. As we see, the object of amended section 3(d) of the Act is nothing but a requirement of higher standard of inventive step in the law particularly for the drug/pharmaceutical substances.' Arguably the confusion is worsened by reference to policy that is not directly borne by the language of S 3(d): 'We have borne in mind the object which the amending Act wanted to achieve namely, to prevent evergreening; to provide easy access to the citizens of the country to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens.' *Novartis v Union of India* Order no: 100/2009 www.ipab.tn.nic.in/Orders/100-2009.htm accessed 2 September 2013. See S Basheer (n 29) 27–28 pointing out that the IPAB did not use expert evidence to determine what the skilled person may or may not have known at the relevant time based on the prior art.

[52] *Novartis* [185]–[187].

[53] *Novartis* [189].

This statement is again an implicit reference to the notional standard of the person skilled in the art and adds weight to the central argument presented here. In this specific case, however, there were no indications or evidence provided to show that the IMBCF would produce an enhanced or superior (therapeutic) efficacy that could not also be achieved by Imatinib Mesylate (non-crystalline form). So the decision turned on the lack of evidence that showed how the 30 per cent increase in bioavailability impacted on therapeutic efficacy.

Bioavailability can present different scenarios during drug development that can speak to how the invention originated. This fact-heavy enquiry in a majority of jurisdictions is firmly placed within the inventive step enquiry. For instance, in the CA decision in *Actavis v Novartis*[54] the fact that fluvastatin was perceived to be much less soluble than it actually was meant that there was no inventive step in making a sustained release formulation of the statin. Here the UK CA relied on perceptions of solubility (and consequently bioavailability) among persons skilled in the art to arrive at a conclusion that is in essence a factual conclusion. In the Board of Appeal decision in T1572/08 *IMMEDIATE-RELEASE PHARMACEUTICAL DOSAGE COMPRISING POLYMORPHOUS TIBOLONE*[55] the inventive step enquiry focused on overcoming the problem of bioavailability as part of demonstrating an inventive step:

> It is [however] customary in the field of drug formulation to micronize poorly soluble drugs in order to enhance their dissolution and absorption in aqueous media […]. The skilled person would regard it as an obvious and straightforward measure to control the particle size and bioavailability when considering known and expected dissolution problems of polymorphous tibolone. Such a selection did not involve an inventive step and the increase in bioavailability shown was not unexpected. This, the subject matter claimed, […] lacked inventive step over document (3).[56]

Different jurisdictions take different approaches to bioavailability within the context of factual inventive step enquiries. The Raloxifene litigation is a useful illustration. The invention in question was a molecule useful for treating or preventing osteoporosis in post-menopausal women but with low bioavailability. A French court found that bioavailability in this case, although a problem, did not constitute a real technical problem but rather was a dosage problem requiring routine work which may take a long time and be expensive but did not imply an

---

[54] *Actavis v Novartis* [2010] EWCA Civ 82.

[55] Available at www.epo.org/law-practice/case-law-appeals/recent/t081572eu1.html accessed 2 September 2013.

[56] [V] Similar facts led to a conjoined decision of Lewison J in *Ivax Pharmaceuticals UK Ltd v Akzo Nobel NV* and *Arrow Generics Ltd v Akzo Nobel NV* [2006] EWHC 1089 (Ch) where, on the evidence, it was found that once the decision had been taken to formulate polymorphous tibolone, finding a particle size with bioequivalence to the marketed product had been no more than a matter of routine testing. The particle sizes claimed were nothing out of the ordinary and it would have been obvious to the skilled but unimaginative formulator that he would formulate polymorphous tibolone of the claimed particle sizes.

inventive step.[57] The US Court of Appeals for the Federal Circuit (CAFC) in contrast decided the other way – that increased bioavailability of Raloxifene was not rendered obvious by the prior art.[58] Specifically, the cited prior art 'exemplified' the bioavailability concerns with Raloxifene, and the skilled worker 'would not have had a reasonable expectation of success in using Raloxifene to treat human postmenopausal osteoporosis.'[59]

In T 0777/08 *Atorvastatin polymorphs/WARNER-LAMBERT*[60] the Board of Appeal of the European Patent Office noted that amorphous forms are generally known to be more soluble and have greater bioavailability than their crystalline counterparts, while crystalline products are generally the easiest to isolate, purify, dry and, in a batch process, handle and formulate. In view of this common general knowledge, a skilled person, starting from the amorphous form of a pharmaceutically active compound as closest prior art, would have a clear expectation that a crystalline form would solve certain specific problems. In this particular case, observing the prejudice the person skilled in the art can be expected to possess,

> The board cannot accept the appellant's contention that the skilled person would be dissuaded from attempting to obtain a crystalline form by the prospect of a potential loss of solubility and bioavailability when compared to the amorphous form. On the contrary, the skilled person would regard this as being a matter of trade-off between the expected advantages and disadvantages of these two classes of solid-state form.[61]

These examples demonstrate two significant observations. First, that complex scenarios presented by bioavailability are commonly dealt with under inventive step enquiries. In the US secondary pharmaceutical inventions are largely dealt with under 'enhanced utility' compared to the base compound. S Raghavan provides two examples of US case law where the CAFC denied patents to derivatives based on this standard.[62]

---

[57] English translation of the French decision is available at http://kluwerpatentblog.com/files/2012/06/2012-0320_TGI_Paris_3_1_Eli_Lilly_c_Teva_translation.pdf accessed 2 September 2013. Here the French court followed an uncited Canadian court in Ottawa.

[58] *Eli Lilly and Co. v. Teva Pharmaceuticals USA, Inc* 689 F3d 1368 (Fed Cir August 24, 2012).

[59] See KE Noonan, 'Eli Lilly & Co. v. Teva Pharmaceuticals USA, Inc. (Fed Cir 2010)' www.patentdocs.org/2010/09/eli-lilly-co-v-teva-pharmaceuticals-usa-inc-fed-cir-2010.html accessed 2 September 2013.

[60] Available at www.epo.org/law-practice/case-law-appeals/recent/t080777ex1.html accessed 2 September 2013.

[61] [5.2].

[62] *Pfizer v Apotex* 480 F 3d 1348. This decision of the CAFC was unexpected as three district courts had already decided that Pfizer's Norvasc patent was non-obvious. In a unanimous decision a three-judge panel concluded that amlodipine besylate would have been obvious in light of Pfizer's own US Patent No. 4,572,909, which discloses amlodipine and related compounds, together with various articles describing besylate salts of different compounds. In *Schering v Geneva* the CAFC used the doctrine of what

Secondly, the case law, such as it exists, shows a varied response to the patentability of secondary pharmaceutical innovation based on aspects such as bioavailability. While this quality can convey considerable information about the process of drug development and consequently the efficacy, including therapeutic efficacy of a drug, evidence of bioavailability by no means equates to an inventive step and enquiry into bioavailability is best undertaken within an inventive step standard broadly conceived.

Thirdly, the Indian Supreme Court here missed a significant opportunity by not plugging S 3(d) into comparative jurisprudence widely extant in other jurisdictions raising serious questions about derivative or secondary pharmaceutical inventions. Had the court done this, it would have actively positioned itself as a persuasive authority not just within developing countries, but possibly also with respect to leading jurisdictions such as the UK, USA and Europe. There can be no doubt that the TRIPS Agreement affords considerable flexibility for India to set patentability standards. To do so, however, with minimum disruption to conventional statutory or methodological frameworks, whilst still achieving the desired result of closer scrutiny of secondary pharmaceutical inventions, would have truly made *Novartis* the post-TRIPS triumph it could have been.

4. CONCLUSION

Based on the discussion here, applying robust patentability standards, whether under non-obviousness or under enhanced utility as in US patent law for pharmaceutical derivatives, cannot be said to be an outlier of the dominant legal position in most jurisdictions. It is very much a part of the 'normal'[63] (as opposed to heightened) tests of novelty, inventive step and industrial application.

Methodologically, the advantages of such approaches within patentability criteria are many. Drawing on the role and attitudes of the person skilled in the art within inventive step assessments allows patent offices and courts to draw on a solid body of case law and perspectives that are tailored to chemical and

---

is already inherent in the prior art. Here the claim was to a metabolite of an existing antihistamine. The court pointed out that failure to recognize that something had been produced previously does not avoid anticipation if that something was clearly produced. For a discussion around these decisions in the context of *Novartis v UOI* see S Raghavan, 'Nothing Wrong with Setting High Standards of Patentability' Interview, available at www.mylaw.net/Article/Nothing_wrong_with_setting_high_standards_of_patentability/#.UiDZNuCafqU accessed 2 September 2013.

[63] Art 27.1 TRIPS.

pharmaceutical compositions and molecules. In this respect use of the person skilled in the art is a crucial and oft used 'policy lever'.[64]

Reversing this to eschew the person skilled in the art to blanket some secondary pharmaceutical inventions under patent ineligibility is unprecedented and remains potentially problematic under the TRIPS Agreement. From the Indian SC's discussion of the genesis of S 3(d) in parliamentary debates, it is easy to appreciate the conclusion that S 3(d) was a special measure. Nonetheless, the SC's adoption of the patent eligibility route has paradoxically left it much less room to manoeuvre the law around secondary pharmaceutical inventions. Exceptions in patent law do not carry the same flexibility that legal determination on inventive step or scope does. As pointed out by a WIPO study on Exclusions and Exceptions, rules of patent eligibility are vulnerable to obsolescence as they have a tendency to become rapidly outdated given opportunistic patent applicants seeking to overcome restrictive terminology.[65]

The decision in *Novartis v UOI* heralds a post-TRIPS coming of age for many jurisdictions like India, including Thailand, Brazil, Malaysia and Indonesia. There is an urgent need to build up legitimate legal standards, tests and principles around domestic patent legislation that do not replicate the predicament around patentability standards that several jurisdictions face.[66] Legal strategies must include transparency that facilitates scrutiny[67] and a body of carefully analysed precedents from own and other jurisdictions.[68] Peter Drahos argues that leaders of the G77 appear to be no longer interested in tackling the global structural disadvantages that the patent system perpetuates as they embrace the patent

---

[64] The term 'policy levers' is used by Lemley and Burk to great effect to refer to flexible legal standards that allow the technology-neutral patent law in theory to function in a technology-specific way in practice. M Lemley and D Burk, 'Policy Levers in Patent Law' UC Berkeley Public Law Research Paper No. 135. Also see G Van Overwalle, 'Policy Levers Tailoring Patent Law to Biotechnology: Comparing US and European Approaches' (2010) *UC Irvine Law Review* 436.

[65] Referring to the work of Professor John Duffy. WIPO Standing Committee on the Law of Patents, 'Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights' SCP/15/3 Annex I 63. Available at http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex1.pdf accessed 2 September 2013.

[66] To cite just two, see J Jacobs' comments in *Actavis v Merck* where the court of appeal reversed its own previous decisions to hold non-obvious and new dosage regimes patentable. [2008] EWCA Civ 444; and the CAFC holding in *Schering v Geneva* 348 F 3d 992 (Fed Cir 2003) that the inherency doctrine is applicable to 'accidental, unwitting and unappreciated' anticipation of metabolites of known substances. Nonetheless, the court was at pains to point out claim drafting techniques that might avoid inherent anticipation (including claiming the metabolite in isolated form and as a pharmaceutical composition). Both of these decisions highlight the (necessary) imprecision that resides within substantive patentability doctrines.

[67] Transparency cannot be taken for granted. For instance, the patent office examination guidelines in Thailand and Turkey are not currently in the public domain. I thank my LLM students Ece Sarica and Nuttada Inchat respectively for bringing this to my attention in the course of their research.

[68] Such as the UKIPO patent examination guidelines – a stellar and invaluable body of research that maps legal tests and standards as well as gaps and ambiguities in case law going back several decades. The guide relating to chemical inventions is available at www.ipo.gov.uk/chemicalguide.pdf accessed 2 September 2013.

system.[69] This argument may be valid for some countries more than others, but what the weaker members of the G77 need most is amelioration of information demands within the patent system,[70] which remain multiple, complex and currently fragmented. In this respect *Novartis* showcases much needed legal pluralism for which the Indian legal system deserves respect irrespective of the missed opportunity that lies at the heart of the decision.

[69] Drahos's argument is based on China, India and Brazil having embraced the patent system as a wealth maximization tool. P Drahos, 'The US, China and the G-77 in the era of responsive patentability' (2012) (4) *Queen Mary Journal of Intellectual Property* 315–328.
[70] Thambisetty, 'Learning Needs' (n 23).