

## Plausibility and Policy<sup>1</sup>

The Rt. Hon. Professor Sir Robin Jacob<sup>2</sup>

In 2006 a new word entered the lexicon of European patent law – “plausibility.” It came from the European Patent Office Technical Board of Appeal (“TBA”) in *Johns Hopkins*.<sup>3</sup> The TBA held that a claimed class of novel polypeptides was unpatentable because the patent disclosed no evidence that the polypeptide actually worked as claimed – it merely asserted that it did. The heart of the reasoning was that the patentee had not, by his unsupported speculation, made any technical contribution: “there is not enough evidence in the application to make [it] at least plausible that a solution was found to the problem which was purportedly solved.” So, it was said, there was no inventive step disclosed – no invention. The same idea (without the use of the word “plausible”) was around before – in the older TBA case of 1995 *AgrEvo*.<sup>4</sup> It decided that a claim to a new chemical class was obvious if there was no technical problem solved. *Johns Hopkins* and *AgrEvo* used the obviousness objection to defeat the patent. The UK used a different route to do the job – insufficiency (see for example, Lord Sumption in *Warner-Lambert*).<sup>5</sup>

That is a bit odd, is it not? How can a plausibility requirement come out of two quite different statutory provisions, neither of which use the word? Moreover, there are glaring gaps in the logic of both routes:

- (i) How can an invention be both obvious and at the same time insufficient? If something would not occur to the PSI (person skilled in the art), i.e. is non-obvious) he/she doesn't get as far as even wondering how to make or do it.

---

<sup>1</sup> Presented at the European Judges; Forum, Virtual Venice, 16<sup>th</sup> October 2020.

<sup>2</sup> Sir Hugh Laddie Professor of Intellectual Property Law, Faculty of Laws, University College London, a former Lord Justice of Appeal of England and Wales. With thanks for assistance from Alexandra Mezulanik and Dr Lynne Chave.

<sup>3</sup> JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE/Growth differentiation factor-9 (T 1329/04). An influential case. For instance, the UK highest court, then called the House of Lords, accepted Johns Hopkins reasoning as regards obviousness in *Conor v Angiotech* [2008] RPC 28, [2008] UKHL 49. Lord Hoffmann at [37] described plausibility from the specification as a “threshold test.” That was not necessary for the decision and so it would be open to a UK court to consider the case of an implausible invention which nonetheless worked. Incidentally, I gave the lead judgment in the Court of Appeal. I am quite satisfied that I was wrong, and that the House of Lords was right, save that, as I have said, it was not necessary for it to adopt, without argument, the plausibility test.

<sup>4</sup> T 939/92 ((Triazoles).

<sup>5</sup> *Warner-Lambert v Generics* [2018] UKSC 56 at [35].

- (ii) Why is a postulated new chemical compound or class of compounds “obvious” if no potential use coupled with some evidential basis is disclosed, but not obvious if such a use and basis is disclosed?
- (iii) Why, if the invention is in fact enabled, is the patent bad for insufficiency if it does not provide plausible evidence that it is enabled?

### ***The Statutory Language***

It is not just of question of logic. If one actually looks at the words of the EPC,<sup>6</sup> a purist would say it is straining the meaning of words beyond breaking point to get plausibility out of them - positively Humpty Dumpty-ish.<sup>7</sup> I suppose it is for that reason that none of the judicial reasoning for getting the notion of plausibility out of either the definition of inventive step (obviousness) or sufficiency has much, or indeed anything, to do with the actual words in the statute. And the word plausibility itself is not in the statute – indeed is not, and never has been, in any patent statute anywhere.

Let us go back to the language actually used. For obviousness, the EPC has two interlinked provisions. Firstly:

#### *Art. 52 Patentable Inventions*

- (1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

If “inventive step” had been left there, undefined, then the TBA’s reasoning in *Johns Hopkins*, which is based on “inventive step” could have had some basis in the statute.<sup>8</sup> But the statute *defines* what is meant by “inventive step” by a second provision:

---

<sup>6</sup> The European Patent Convention 1972, implemented by each of the initial contracting states in 1977 and when the European Patent Office first opened its doors.

<sup>7</sup> “When I use a word”, Humpty Dumpty said in rather a scornful tone, ‘it means just what I chose it to mean – neither more nor less.’ *Alice through the Looking Glass*, Lewis Carroll.

<sup>8</sup> Although even then a different view could have been taken – namely that the patentee who first proposes a new compound or class of compounds and postulates a use (as it turns out correctly) has indeed made an invention at that moment.

### *Article 56 Inventive step*

An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

The test for inventive step *is* non-obviousness, not some wider consideration involving a technical contribution. or an inventive step in some more general sense. If what is claimed is not obvious, the statute says it involved an inventive step. *Johns Hopkins* and *AgrEvo* reasoning is the other way round: that because there is no inventive step, an invention is obvious. That is actually rather illogical as well as contrary to the words of the statute. *Johns Hopkins/AgrEvo* reasoning will not do.

What about getting the plausibility requirement from sufficiency, the route espoused by the UKSC in *Warner-Lambert*? Well again the language of the statute hardly supports it. The relevant language is Article 83:

### *Article 83 Disclosure of the invention*

The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art

This merely requires that the psi must be able to “carry out” the invention using his/her CGK (common general knowledge) and the information in the patent. Arnold LJ called an inability to carry out the invention<sup>9</sup> “classical insufficiency” in *Akebia Therapeutics*.<sup>10</sup> He went on to say that two other forms of insufficiency fall within the objection, so-called *Biogen* insufficiency (excessive claim breadth) and ambiguity (also called “uncertainty”). Both of these indeed fit the language of Article 83: they are really particular cases of classical insufficiency rather than separate distinct forms of it. In each case the PSI cannot make what is claimed or all of what is claimed.

I elaborate. In *Biogen* the claim was in for a “recombinant DNA molecule” having specified characteristics. The molecule itself was known and obtainable by non-recombinant methods. “Recombinant” meant made by a recombinant method. So the inventor of one particular recombinant method was claiming the same known molecule made by *any* recombinant method, methods which owing nothing to his method as described in the patent. The patent did not disclose in a manner sufficiently clear and complete (indeed at all) a recombinant molecule

---

<sup>9</sup> It is well and uncontroversially settled that this means either an inability at all or only with undue effort.

<sup>10</sup> [2020] EWHC 866.

when made by any method other than that which he described.<sup>11</sup> That fits with the statutory language.<sup>12</sup>

Arnold J's "third" form of insufficiency, ambiguity/uncertainty, also fits the words of the statute. If the claim has no meaning at all – not merely is difficult to construe – then the PSI cannot know how to carry out the claimed invention. Of course, true ambiguity/uncertainty is very rare,<sup>13</sup> unlike disputes over claim construction.

Arnold LJ did not include, as a fourth type of insufficiency, lack of plausibility. He might have done on the basis of UK case law, though not of TBA case law. For present purposes it does not matter – whatever the route a plausibility requirement has become entrenched in European patent law notwithstanding it does not fit the words of the statute.<sup>14</sup> Indeed so much so that, by 2018, the position had been reached where the TBA could and did say:

It is however a *conditio sine qua non*<sup>15</sup> that it is shown the technical problem underlying the invention was at least plausibly solved at the filing date.<sup>16</sup>

### ***The Policy(ies) Behind the Plausibility Rule***

There are at least three inter-related policies at work. The principal policy is that the patentee must have disclosed a technical contribution *in his patent*. He must have added to the stock of human knowledge by what is written there. The second policy is based on a perceived danger of precluding research into the territory covered by the patent claim. This policy is stronger the wider the claimed territory – a large Markush<sup>17</sup> claim rather than a claim to a particular chemical for instance. The third policy is more visceral, perhaps appealing more to an outsider

---

<sup>11</sup> Actually the best description of the case and what was decided is by Lord Hoffmann sitting in the Court of Appeal in *Lundbeck v Generics* [2008] EWCA Civ 311 at [32]-[34]. I was a member of the Court. We were upheld by the House of Lords [2009] UKHL12.

<sup>12</sup> And makes eminent sense.

<sup>13</sup> Years ago I invented the example of the lie-detector which had to be calibrated in Pinocchio units, but no-one knew what they were, *Milliken v Walk Off* [1996] FSR 292.

<sup>14</sup> An intellectually better (but not satisfactory) route of construction to get to a plausibility requirement out of the statute is to say that the absence of plausibility means the patentee has simply not disclosed "an invention" at all. Notoriously the EPC never itself defines "invention." Would it be open to a court to say no plausible disclosure in the specification means no invention at all thereby taking the purported patent outside the whole system? There are answers to that. Firstly as I have pointed out above, the EPC deems the non-obvious to involve an inventive step. You can hardly say that that which involves an inventive step is not an invention. Moreover, many judges would say that because the EPC itself contains a considered list of things which are not to be regarded as inventions (Art. 52(1)), it is not for them to create any others.

<sup>15</sup> Putting it in Latin conveys an extra sense of solidity about the proposition – conveying a sense of established since ancient times – set in stone.

<sup>16</sup> *BRISTOL-MYERS SQUIBB/Dasatinib* T488/16 [2019] EPOR 24 at [49].

<sup>17</sup> A form of claim which shows a general structural formula structure with a variety of possible elements or substituents at various positions. Named after a US case, *Ex parte Markush*, 1925 Dec. Comm'r Pat. 126, 127 (1924).

(such as a non-specialist judge who has no experience of the living patent system or how research is actually done). It is an instinctive feeling that somehow it ought to be wrong for a man to get patent for a mere hunch. Emotive words are deployed. Phrases such as “mere speculative” patents or “armchair patents” are used.<sup>18</sup> The notion of the so-called “patent bargain” forms part of these policies. The patentee ought not to get a monopoly without having given the public value in return. In Victorian times, the bargain was seen as analogous to the notion of consideration in a contract<sup>19</sup> – the grant of a patent being a sort of social contract between the patentee and the state.<sup>20</sup> Another word used in older cases was that the monopoly must “equiparate” with the consideration.<sup>21</sup>

These policy(ies), based as they are on a requirement of disclosure in the patent itself give rise to a significant consequential rule: that if the specification does not itself, *ab initio*, provide at least plausible evidence that the invention works, the patent is bad. It does not matter if the patentee can, by later evidence, show he was right. Thus, in *Warner-Lambert*, the patentee asserted in the patent that pregabalin worked as a painkiller for three kinds of pain, inflammatory pain, central and peripheral neuropathic pain. And it in fact did - for all three types. But the patent itself only had evidence making use for inflammatory pain and peripheral neuropathic pain plausible. There was nothing in the patent to support the assertion it worked for central neuropathic pain – apart of course from the patentee’s say so. The fact that he was proved right did not help.

### ***Was Plausibility Part of Patent Law Before the EPC?***

If plausibility is a *sine qua non*, is so absolutely fundamental, one wonders if and how patent law managed without it in earlier times. Was it there albeit under some other name? If the rule was absent or existed only in an attenuated form (particularly without the requirement of disclosure of plausible material in the patent itself), the current entrenched view is surely called into question. Why should it be entrenched now, if for nearly two centuries of active patent

---

<sup>18</sup> “It is designed to prohibit speculative claiming, which would otherwise allow the armchair inventor a monopoly over a field of endeavour to which he has made no contribution,” *per* Floyd LJ. Actually, I think the expression “armchair invention” was coined by Pumfrey J in *Cipla v Glaxo* [2004] EWHC 477 (Pat) at [116], see below.

<sup>19</sup> English contract law says that each party must give something of value to the other for a contractual promise to be binding.

<sup>20</sup> The older English cases use the word “consideration.”

<sup>21</sup> For example, Lord Allness in *Mullard v Philco* (1936) RPC 323.

law,<sup>22</sup> there was either no such rule or a less stringent rule and patent law nonetheless worked well to promote innovation?

So what was the past position? I can only speak on UK law. However, I am not aware of any discussion of a plausibility rule under the patent law of any other country in pre-EPC days. If such a rule had been significant, I suspect I would have come across it because I was quite often concerned with parallel litigation about members of the same patent family. Moreover of course, many of the UK patents concerned will themselves have been granted pursuant to convention applications which means the basic technical text will have been the same as in the UK patent. Thus the plausibility or otherwise of the disclosure, if it had really mattered, would surely have been contested under many different patent laws. Patentees would have taken steps, if they could, to include in their patents detail to give their assertions of utility plausibility. As will be seen they did not.

The question of a plausibility requirement almost always arises in the context of chemical patents, mainly in the case of patents for medicines (both new and second medical use). In the case of mechanical patents, it is almost always clear what the invention is for, how to construct it and how it works. If it can be made, it will plausibly do the job the inventor says he made it for. But even in the case of mechanical inventions a plausibility objection could have arisen in the past: some inventions have to be seen to be believed.

#### *Terre Armée (Reinforced Earth)*

I had one such case. Around 1982, I appeared for the inventor of “reinforced earth” (“terre armée”), Henri Vidal. It was an invention which seemed incredible – indeed remains counter-intuitive now. Every kid on a beach knows that if you make a pile of dry sand,<sup>23</sup> you cannot get the sides of the pile to be more than a certain angle. The “angle of repose” is just above 30°. If you put more sand on the top it just slides down leaving the same angle. Henri, a bit bored on a Mediterranean beach, played with long needles from the umbrella pine trees at the back and sand. He saw that if he made a pile but included layers of parallel spaced (horizontally and vertically) needles, the angle of repose increased. After home experiments,<sup>24</sup> he came up with

---

<sup>22</sup> Until the industrial revolution got going in the late 18<sup>th</sup> century, patents for inventions, were few in number.

<sup>23</sup> Wet sand and clay behave very differently.

<sup>24</sup> We repeated one in court – a vertical wall about 3 feet high made with dry sand, with layers of 1-inch strips of newspaper spaced apart, the layers spaced apart vertically by about 1.5 inches and the strips spaced apart horizontally by about the same amount. The front edge of the wall had some strips of newspaper bent in a curve between each layer just to stop the sand running out. We put an articled clerk (as trainee solicitors were called) to stand on the wall. No defence could survive that!

a somewhat incredible theory – that friction forces between the sand particles were somehow transferred through the sand particles to the needles. He worked on models at home, thinking his idea could be used to build real walls. He applied for and got his patent.<sup>25</sup> It was very difficult to get people to believe him at first. However, notwithstanding what at the time was seen as a very shaky theory, it works. Now there are reinforced earth structures all over the world, mainly road or rail embankments and bridges. Look for tessellated cruciform panels of concrete. You cannot see from outside, but the panels are quite thin – just enough to stop the sandy material from running out. The inside face of each panel is attached to thin, spaced-apart strips of steel running back in the sandy material. The whole thing just stands up. Before this invention, if you wanted a vertical wall to hold back earth or for a bridge, you had to make heavy strong foundations to keep back the sandy material. With terre armée no foundations are needed. Cost savings are immense. There are other benefits too.<sup>26</sup>

Would the terre armée patent have survived today on the basis that it lacked plausibility? Lord Sumption in *Warner-Lambert* said:<sup>27</sup>

In the case of a patent for a new product or process, that assumption [i.e. that an invention will be sufficiently disclosed if the specification enables it to be performed] is almost always correct. The skilled person will discover that it works by replicating it in accordance with the specification.

So, it might be said, if you tried out what Vidal said in his specification even if you thought it probably would not work, you would find out that it indeed worked so the patent was sufficient. But once it is conceded that trying out what the patent says for a new product or process can confer sufficiency, there is no logical stopping place. Why should a second medical use patent be different? After all, Warner-Lambert said in its patent that pregabalin would work for central neuropathic pain. If the PSI tried that, he would find it was so. Why should it matter (as Lord Sumption thought it did) that “the knowledge which made the identification of the new purpose inventive” be actually disclosed? What if the “knowledge” is only a hunch by the inventor?

---

<sup>25</sup> UK 1,069,361 based on a French application in 1963. Figures 3 and 4 show what we built in court with paper and dry sand.

<sup>26</sup> Earthquake resistance (it flexes rather than breaks as solid concrete would be liable to do), easy to dismantle and easy to put up.

<sup>27</sup> At [19].

## *The Old Law*

Under the old law product claims could not cover any product which was old, even if a wholly new and inventive use had been found. The fiction that a new use could confer novelty on an old product when it was for the new use had yet to be devised.<sup>28</sup>

Against that basic position, what rules of patent law which might have included plausibility existed under pre-EPC law? The candidates are the common law rules which came to codified<sup>29</sup> under the names “utility”<sup>30</sup> and lack of fair basis.<sup>31</sup> Sufficiency can be ruled out – in those days it really did mean just lack of sufficient instructions as to how to perform the invention, no more.<sup>32</sup>

### *Utility under the old law*

This, somewhat varying, concept has long been an underlying idea behind many patent laws. A strict view was that a patent should be a kind of blueprint – it must give the PSI enough information to practice the invention at once. Only then was it considered useful. And only if it did that was the patent providing enough information to fulfil the patent bargain. One might call this a Dragon’s Tooth requirement – from the Greek legend that if you sowed a dragon’s teeth, they immediately sprang into fully armed warriors ready to fight.<sup>33</sup> An example of this view is in the Statute of Venice 1474 which only permitted the patenting of a device “when it has been reduced to perfection so that it can be used and operated.”<sup>34</sup> And from 1790 to 1880, the US Patent Office not only required a description and detailed drawings but also miniature models of the invention.<sup>35</sup> Softer requirements of inutility were developed, otherwise the patent system could really only work for mechanical devices. The concept of sufficiency ate into that of utility – if there were sufficient instructions to enable the PSI to perform the invention it did

---

<sup>28</sup> It first surfaced at the EPO in 1990 in *MOBIL/friction reducing additives*, T 59/87. Swiss form claims for patenting old medicines for new uses was a logical development.

<sup>29</sup> By the Patents and Designs Act 1932.

<sup>30</sup> PA 1949 s.32(1)(g): “the invention, so far as claimed in any claim of the complete specification, is not useful.” There are plenty of cases about inability to perform, a well-known example *Mentor v Hollister* [1993] RPC 7, is still cited under the 1977 Act.

<sup>31</sup> PA 1949 s.32(1)(i): “... or that any claim of the complete specification is not fairly based on the matter disclosed in the specification.”

<sup>32</sup> PA 1949 s.32(1)(h): “that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed.”

<sup>33</sup> Jason defeated them by throwing a stone in their midst. Accusing each other, they fought until all were dead.

<sup>34</sup> There are various translations of the original which is in an obscure Venetian dialect, see Ikechi Mgbegi, *The Juridical Origins of the International Patent System*, *Journal of the History of International Law* 5.2 (2003): 403-422, a superb article.

<sup>35</sup> USPTO Press Release *Patent Models: Icons of Invention* February 11<sup>th</sup>, 2002 sets out a brief history.



not matter if the instructions did not spell out every detail. By the early part of the 20<sup>th</sup> century, what remained of the inutility objection was this: that if the patent claim included matter which would *in fact* not work, either at all or as promised by the patentee, only then was it invalid for inutility.

Some examples illustrate this. In *Hatmaker v Nathan*,<sup>36</sup> the patent was for dried milk made by the process described in the patent. The patent said “The dry milk solids obtained by my process ... are in so perfect a state that they can be restored to milk of excellent quality by the addition of hot water.”<sup>37</sup> That was not in fact true, though the process did produce a usable product, the defendant’s product<sup>38</sup> being one of them. The patent was invalid for want of utility. The important point for present purposes was that the inquiry was whether or not the patentee was actually right in his assertion, not whether the assertion was credible. *May & Baker v Boots*,<sup>39</sup> was a very early mighty pharma case of the kind which are now so familiar.<sup>40</sup> The patent claimed a large Markush class of sulpha products.<sup>41</sup> It said they had “chemotherapeutic value in streptococci infections and similar illnesses.” Two particular members of the class were described along with the results of mice experiments showing this. As to other members of the claimed class, the evidence was that in fact some would not work, and no-one had any idea whether others would or not. The class claim was held invalid for want of utility.<sup>42</sup> For present purposes what matters is that the case did not turn on plausibility from the patent itself.

A requirement of plausibility solely from the information in the patent was thus not a part of the law of utility before 1977. If the invention in fact worked as the patentee promised, it was useful. If not, not.

---

<sup>36</sup>(1919) 36 RPC 231 (HL). An early “patent troll” case. The patentee had bought the patent and corresponding patents in other countries to sue upon them – and with some success in Germany and France. He probably ran out of money though – at first instance he was represented by Sir John Simon KC, a leading QC of the day. In the HL he represented himself.

<sup>37</sup> There were other representations challenged but this was treated as the key one.

<sup>38</sup> Trade mark Glaxo: the Nathan company was a New Zealand company before being absorbed into what is now GlaxoSmithKline.

<sup>39</sup> (1948) 65 RPC 255 (Jenkins J).

<sup>40</sup> The trial took 16 days. Even in the House of Lords, (1950) 67 RPC 23, it took 11 days. And there it was only concerned with the amendment point

<sup>41</sup> The sulphonamides, the first of which found by Bayer in 1932, were the first artificial antibacterials, the predecessors of penicillin.

<sup>42</sup> Oddly to modern eyes at least, there were no claims to the specific embodiments. An attempt to amend down to these was refused as impermissible under the then rule that amendment was not permissible if the result was to claim a different invention – from a generic to a specific invention. The appeals to the CA and HL were solely on the amendment point.

### *Lack of fair basis*

I turn to examine the other possible candidate for containing within it a plausibility requirement, namely lack of fair basis. Here is only necessary to go to one case, *Olin Mathieson v Biorex*.<sup>43</sup> The patent claim was for a large Markush claim, a feature of which was a -CF<sub>3</sub> substituent in the 2-position of a three-ring structure called a phenothiazine. A prior art phenothiazine, chlorpromazine, had a -Cl in the 2- position and was known as a tranquiliser. All the patent said about the new class was:

The ... phenothiazines of this invention and the acid-addition salts thereof are therapeutically active compounds which are utilizable as antihistaminic, antiemetic, and especially tranquillizing (or ataractic) agents. Thus, [a particular phenothiazine within the claimed class] is more potent than chlorpromazine as a tranquillizing agent.<sup>44</sup>

No data was supplied to support this assertion.<sup>45</sup> However, the evidence, based on post- patent data, established that one could make a sound prediction that what the patentee said was true. Graham J said<sup>46</sup>:

But if it be true, and it appears to be so from works such as those of Sexton and Robson & Stacey subsequent to the date of the patent, that such enhanced activity is obtained by the use of the -CF<sub>3</sub> substitution, then it is clear that the plaintiffs have in fact contributed, and indeed contributed considerably, to the common stock of human knowledge by their invention, even if the promise in their specification can as a matter of words be said to guarantee nothing more than the therapeutic activity which is said to be the characteristic of all phenothiazines. In my judgment, it is what the patentee has actually achieved and not what he has promised (provided, of course, his promise is not false) which matters from the point of view of consideration and subject-matter in the sense of inventive merit.

He held that if a sound prediction *based on the current (i.e. post-patent) evidence* could made that all of the claimed class worked, that was enough – the patent bargain was satisfied. There was no requirement of plausibility based solely on the patent disclosure. The only data in the patent<sup>47</sup> were 10 examples showing how to make 10 members of the claimed class plus the assertion that one of these was more potent than chlorpromazine. The reader might infer that the patentee had actually conducted a comparative test which showed higher potency,<sup>48</sup> but it

---

<sup>43</sup> [1970] RPC 157.

<sup>44</sup> The specification is printed in full in the case report.

<sup>45</sup> I think I recall that the patentee in fact had some data, but did not even think it necessary to put it in the patent.

<sup>46</sup> p.125.

<sup>47</sup> Printed in full in the report at [1970] RPC 157, 157-167.

<sup>48</sup> It is also my recollection (I was second junior). The test was called the “mouse rage” test. You put mice on a conducting surface and gave them shocks. Each blamed the others and they fought. A dose of tranquiliser stopped

is doubtful whether the patent would have survived the current plausibility test. All there was to go on was the patentee's assertion.

*A wrong theory did not matter*

One further point deserves discussion. It was well settled that if an invention actually worked as described by the inventor it did not matter if he had arrived at it by a wrong theory. This was settled by *Electric Lamp v Marples*.<sup>49</sup> The invention was an improvement in tungsten filament bulbs. These blackened in use. Conventional wisdom was that this was caused by carbon, a minor constituent of the tungsten filament. The invention was a process to decarbonise the filaments by the use of phospham. The patent said the treatment removed "the last traces" of carbon. Post-patent research established that most of this was not true. The blackening was caused by tungsten, not carbon. Nor was all the carbon in fact removed by the patented process. But it was the carbon in the filament which promoted the volatilisation of tungsten. And although all the carbon was not removed, enough was removed to prevent the tungsten from volatilising. The Court said none of this mattered. The invention worked. From the point of view of plausibility, the wrong theory made the invention plausible. If people had known the blackening was tungsten, the invention would have been implausible, unless they also knew that carbon above a certain level caused the tungsten to volatilise. Without worrying about any theory, the patent told you what to do and it worked. No question of plausibility came into it.

*The textbooks*

As far as the textbooks were concerned, again there was no suggestion of a plausibility test. T.A. Blanco White, whose book was rather more thoughtful than the rival *Terrell*,<sup>50</sup> considered the "sound prediction" test.<sup>51</sup> He was somewhat critical, saying:

it is open to question on two grounds: that it is not easily reconcilable with the proposition that 'fair basing' is a matter arising only on the contents of the complete specification; and that it is fundamentally unsound to judge inventors by a standard of what other people might have predicted (which it is probably what it amounts to).

---

the fighting! For the trial a few more examples (not in the patent) were made and tested – to boost the sound prediction.

<sup>49</sup> (1910) 27 RPC 737, CA.

<sup>50</sup> In those days *Terrell* deliberately tried to set out the law as though it was all settled. There was no discussion of uncertain points, indeed hardly a hint that any aspect of patent law was controversial. The modern *Terrell* is much more thoughtful.

<sup>51</sup> *Patent for Inventions* 4<sup>th</sup> Edn. 1974 at p.82, paragraph 2-304, the last pre-EPC edition.

Despite that criticism, Blanco White was far from endorsing anything like the modern plausibility test. He went on to propose what I will call the “pudding taste” test:

The more generally useful approach might be that the proof of the pudding should be in the eating: if the inventor is able to say ‘I did predict that the others would work’ and nobody is able to show any instance in which he was wrong, that should be enough.

Blanco White also of course had something to say about speculative claims:

It is not permissible to include in a claim an ‘unexplored field’, which it is impossible to predict how much of what is within will be useful and will incorporate the inventor’s own discovery.<sup>52</sup>

The authority Blanco White gives for this is sparse, a Patents Appeal Tribunal case, *Shell Development*<sup>53</sup> and a Solicitor-General case, *Esau*.<sup>54</sup> Shell had an outrageously wide claim – a process for separating a mixture of *any* organic compounds by the use of a particular solvent. Given that there were just a few examples Wynn-Parry J had no difficulty in saying the claim was “broad and indeterminate” and “speculative.” He applied patent bargain reasoning saying: “The consideration which the patentee gives is the disclosure which he makes and his monopoly, as I see it, cannot extend beyond what is necessary to protect what he discloses.” In modern parlance the claim was not merely “not plausible”, it was implausible. From the sparse report is not even clear that the patentee asserted that everything within the claim would work.

Another and strong indication that in pre-EPC times plausibility was not a *sine qua non* is *T.S.’s Appn*.<sup>55</sup> and its aftermath. In 1923, the Solicitor-General<sup>56</sup> allowed an appeal from the Comptroller who had refused a patent for a perpetual motion machine. The S-G held there was no power to do so. Not even *implausibility* was a bar to patentability – miles away from a requirement of plausibility.<sup>57</sup> Some were irked by this. The Sargent Report<sup>58</sup> which led to the Patents and Designs Act 1932, recommended that the Comptroller should be given a power to

---

<sup>52</sup> Para. 2-305 p.83.

<sup>53</sup> (1948) 65 RPC, Wynn-Parry J.

<sup>54</sup> (1932) 49 RPC 85.

<sup>55</sup> (1921) 61 RPC 530. The judgment is well worth reading.

<sup>56</sup> Sir Henry Slesser, later Lord Justice Slesser. Law Officers were heavyweight lawyers in those days.

<sup>57</sup> The S-G did make a reference to utility – and surely if the patent was granted it could have been revoked for lack of utility since the promise of the patent would be unfulfilled. For obvious reasons, no-one would have bothered to do so, however.

<sup>58</sup> *Report of the Departmental Committee on the Patents and Designs Acts and Practice of the Patent Office*, Cmd. 3829, 1931.

refuse the grant of patents for alleged inventions contrary to well-established natural laws.<sup>59</sup> That was accepted and enacted. The provision was repeated in the 1949 Act.<sup>60</sup>

Finally, as regards pre-EPC law is concerned, it is worth looking at some actual pharma patents to see to what extent they contained “evidence” to support the patentee’s assertion of utility. I have already shown that the Olin Mathieson patent had no “evidence” (by which I mean here reported experimental data as opposed to the mere assertion of a utility by the patentee). It was not atypical: other pharma patents,<sup>61</sup> though by no means all,<sup>62</sup> also had bare assertions of utility. Some asserted that the patentee had found the utility, but you only had his word for it with no data or indeed how he had found out. I doubt that either would be enough now. The modern law requires more - the patentee must put into his patent:

corroborative detail, intended to give technical verisimilitude to an otherwise bald and unconvincing narrative.<sup>63</sup>

The upshot is that the previous law was indeed less strict than now. It was miles from a Dragon’s tooth test – it was a pudding taste test. If a patented invention did “exactly what it said on the tin”,<sup>64</sup> the patent would be upheld. There is, as far as I know, no case where the invention in fact worked but the patent failed for want of plausibility from information of the patent.

I turn back to the policies for the current rule which I set out above. I suggest they are too crude, too limited. The result of their application is that some good inventions are not getting protection. Warner-Lambert lost their patent for advancing the idea, without experimental evidence, that pregabalin worked for treating central neuropathic pain. Even though it was a good idea. Similarly, also for Johns/Hopkins, though they proved their invention was plausible.

I question the basic assumption – that one starts with the notion of the patent bargain being disclosure for monopoly should be the sole source of policy. The overreaching policy should

---

<sup>59</sup> p.8, para. 21-22

<sup>60</sup> Section 10(1) “If it appears to the comptroller in the case of any application for a patent – (a) that it is frivolous on the ground that it claims as an invention anything obviously contrary to well-established natural laws ... he may refuse the application.”

<sup>61</sup> For example, UK 869,457 (Hoffmann-La Roche) claimed a combination of chlordiazepoxide (a tranquilliser) and pentaerythritol nitrate (an angina drug). The only “evidence” supporting the inventiveness was this: “It has been found that chlordiazepoxide when used in combination with pentaerythritol tetranitrate enhances the activity of the pentaerythritol tetranitrate in reducing the number and extent of angina attacks. This is surprising since chlordiazepoxide alone exhibits no known effects on the heart.”

<sup>62</sup> For example, the 1962 Boots’ patent for ibuprofen (UK 971,700) reported mice tests and a small clinical trial.

<sup>63</sup> With apologies to WS Gilbert the author of the lyrics of the Mikado. I have substituted “technical” for “artistic”.

<sup>64</sup> This slogan, used in UK TV advertisements from the 1990s for products such as varnish and wood-stain, has passed into the language.

surely be that patents should be granted for anything new, non-obvious and enabled which advances, or might advance, technical progress. The days are long gone when patents can only be granted for Dragon's tooth inventions. To be patentable an idea does not have to be "oven-ready" any more. Lord Sumption in *Warner-Lambert* speaks<sup>65</sup> of the notion of plausibility being a "mitigation of the principle" "that the patent must disclose some reason for supposing that the implied assertion of efficacy is true." He says the "mitigation" is "in favour of patentability" because of "the practical difficulty of demonstrating therapeutic efficiency to a higher standard at the stage of when the patent application must in practice be made." Lord Sumption clearly in principle favoured a "Dragon's tooth" requirement and only grudgingly concedes that a lesser standard will have to do. Even then his stopping point is a standard of plausibility which is higher than Floyd LJ's "prediction ..based on the slimmest evidence" test propounded in the Court of Appeal.<sup>66</sup> Lord Sumption says there must be some reason to suppose the assertion is true, not merely may be true.

This is understandable if one's policy towards regards patents is based on strict view of the patent bargain theory. But the theory of course has no actual statutory basis. Moreover, it is not well-related to the real world of research, particularly in the pharma field. Research is expensive and most things that are tried lead to failure. This applies not only to research which producing nothing promising, but also that which does and leads to patents. Few pharma patents actually lead to real practical medicines.<sup>67</sup> Patents for uncertain prospects (whether for new compounds or second medical use) are an essential reality of the system. They are the incentive for developing an idea into a real product. Permitting them is not a grudging concession – it is an incentive for innovation. And the higher you raise the requirement of disclosure in the patent itself the less the incentive for testing an idea.

There is also quite a strong policy case for permitting patents for ideas alone, without the addition of a limited plausibility test that the idea might work. Pumfrey J thought so: "It has to be remembered that a perfectly valid patent may be written by a person who does not stir from

---

<sup>65</sup> At [36].

<sup>66</sup> [2016] EWCA Civ 1006 at [46].

<sup>67</sup> It would be a good exercise to compare pharma patents applied for which lead to actual medicines which have passed Phase III trials and reached the market.

his armchair, thinks it is all obvious [that must be to the inventor himself<sup>68</sup>] and does no experiments to confirm his hunch.”<sup>69</sup>

Firstly, a major consideration, missed by a strict requirement for plausibility from the patent itself, is that if the patentee’s hunch turns out to be no good, it is unlikely that anyone will be harmed or disadvantaged. The patentee will have lost his investment in trying to prove his idea works but because it turned out to be no use, no-one will want to do it. In the real world the patentee of an invention that does not work will simply not renew his patent for it only gives him a right to prevent others doing what can’t be done anyway.

A second reason favouring a mere hunch being enough comes from considering the attributes of the inventor. Unlike the PSI, he is inventive. Unlike the PSI, he may have no skills in the relevant art – he can be a complete outsider, blundering on the invention precisely because he is not inhibited by the CGK of the PSI. Unlike the PSI, he may base his idea on a completely wrong or unaccepted theory, bad science. None of that should matter if he has in fact come up with a valuable and useful idea. Whether he has or not may well require testing and development. Most inventions do anyway. Is it not better to give him a patent so he has an incentive to test and develop, rather than leave the field unexplored?

This last point has support from some economists. Kitch called it the “prospect function” of patents,<sup>70</sup> drawing an analogy with exclusive mineral prospecting licences. The more limited “patent bargain” theory he called “the reward function.” Another name for the prospect function is “development rights”.<sup>71</sup> Of course not all economists agree,<sup>72</sup> but Kitch’s view is largely based on his examination of real-world patents and inventions – i.e. it is really world evidence based. One only has to ask oneself why a pharma company would invest of the order of \$1 billion<sup>73</sup> in taking a mere plausible idea through all the development involved over around

---

<sup>68</sup> If he thought his idea was obvious generally, he wouldn’t think he had made an invention at all, still less tried to patent the idea.

<sup>69</sup> *Cipla v Glaxo* [2004] EWHC 477 (Pat) at [116].

<sup>70</sup> *The Nature and Function of the Patent System* Edmund W. Kitch. *Journal of Law and Economics*, Vol. 20, No. 2 (Oct., 1977), pp. 265-290. This is regarded as a seminal article on the topic.

<sup>71</sup> Steven N. S. Cheung, *Property Rights and Inventions: An Economic Inquiry* 17 (mimeo May, 1977).

<sup>72</sup> Do they ever? Some of the disagreements are summarised in *Rethinking the Prospect Theory of Patents*, John F. Duffy, *University of Chicago Law Review* 2004, p.399.

<sup>73</sup> Estimates vary but all that matters for present purposes is that it is a huge sum.

12 years if it had no patent protection once the medicine was proved to work and be safe to see that there is much in Kitch's view. Kitch's critics are more abstract, more theoretical.<sup>74</sup>

There is another, more metaphysical, question involved too. When is an invention made? When the inventor has the idea? When he has tested his idea to the point that there is objective evidence that it may work? Or is likely to work? Or does in fact work? The possible spectrum is from armchair to Dragon's tooth. The current position, that armchair without some experimental evidence or some plausible theory is not enough, is not self-evident. After all armchairs are often the very place where people have good ideas.

Finally, there is something intrinsically odd about the plausibility requirement. The thought seems to be that if the patentee asserts something works, he should not be believed *unless* he gives some experimental evidence making the to support the assertion or theory supports it. Why is the patentee's word not enough? And why, if is not enough, does his word about experiments make him more plausible? Suppose he says he has conducted experiments which support his idea but does not give the detail? Or suppose his assertion can be readily tested by the PSI? Surely it should be enough that his idea can be verified without undue effort<sup>75</sup>.

A rational way out of all this is to say that the patentee's assertion *does* add to the stock of human knowledge, unless that assertion is *not* plausible or cannot readily be tested. Scientific knowledge is not a black and white thing, true or not true. "Knowledge" is much more nuanced. Ideas, even unsubstantiated, can be valuable. And people (even patentees) should not be taken to be liars or even wrong in what they say without evidence. Valuable inventions which in fact work would be protected. Useless ones would fail on their merits or rather lack of merit. Patents for them would not matter and most, if not all, would be abandoned well before their 20-year term. We would be back to a "pudding taste" test. Patents for what proved to be good ideas would be valid. Patents for useless ideas would just not matter.

A more realistic "patent bargain" theory supports this approach. The classical theory was devised back in the nineteenth century in the time of only Dragon's tooth patents. After expiry of a Dragon's tooth patent, the public are entitled to use what was disclosed in the patent, i.e.

---

<sup>74</sup> E.g. *Patent Prospect Theory and Competitive Innovation*, Erik Hovenkamp, <https://ssrn.com/abstract=2765478> (2016).

<sup>75</sup> The TBA in *BRISTOL-MYERS SQUIBB/Dasatinib* T 488/16; [2019] E.P.O.R. 24 at [4.9] said that what mattered was "the absence of any verifiable data with regard to the asserted technical effect." But why should this matter if the PSI could verify without the patentee's data or could verify in some other ready way?



that which then was more or less a blueprint. What the public got is only what the patentee described. Although that is still sometimes the case, it is generally not, especially in the case of pharma patents. For what the public gets on expiry is *much* more than what the patentee has disclosed in his patent. Take the case which everyone agrees passes the plausibility test – a patent which discloses some plausible data that the idea might well work. The patentee is still miles away from showing that it does in the real world and is safe. If he invests in a huge, expensive and lengthy process and eventually proves it is safe and works he will be lucky to have 10 years exclusive rights.<sup>76</sup> So when those rights expire the public will get much more than was in the original patent – it will get the result of all the post-patent work done by the patentee. I suggest the patent bargain policy should not be based on just a notional deal between patentee and public at the time when the patentee gives the public just the information in the patent in return for his monopoly for the future. It should be based on what he will in fact give the public when the patent expires or ceases to be in force. That will either be a fully-developed and so valuable invention, or just the information that the invention, does not lead anywhere.<sup>77</sup> Graham J was right in *Olin Mathieson*. The “consideration” received by the public should take into account the value of post-patent research which proves the idea is valuable.

What then of the other policy reasons for the *sine qua non* approach? Preclusion: that the grant of a patent with no experimental or theoretical evidence making the invention plausible will preclude research by others. Is that really so? Consider first a very narrow claim – say to a single substance which the patentee says, based only a hunch, will have particular, identified, beneficial properties. Preclusion, if it existed at all, would be only of a very narrow field. It would be more than offset by the research incentive on the patentee to back and invest in his idea. Now consider a very wide claim. It would be of doubtful validity as being implausible.

More generally however, has the preclusion theory any basis in fact? I seriously question that. In the real world, I have never heard of patents deterring research. There is evidence against the idea too. In reality, major inventions are frequently followed by a mass of improvement patents not merely by the patentee but by others. It is also very doubtful that people apply for patents for things which they have no idea will work or not – there will at least be a hunch behind the patent, a hunch sufficiently strong to warrant the cost and time of patenting. Before

---

<sup>76</sup> Including SPC “extension” of up to 5 years on top of the patent term of 20 years.

<sup>77</sup> In the real world that will become apparent sooner than 20 years from the date of application of the patent. Once research shows the idea will not work, most patentees will let the patent lapse. It is a pity that pharma companies do not disclose their failed research programs, but even without that, abandonment of a patent speaks volumes, as does the absence of any new product covered by the patent.

one makes a policy based on a hypothesis (here preclusion) it should be tested to see whether it accords with reality.<sup>78</sup>

The third “policy” is gut reaction – that a patent for a mere unverified hunch is just too speculative to be allowable. This is difficult to discuss refute precisely because it is based on a gut reaction. It means saying that having the idea without more means the invention has not yet been made.

In the world of patent office officials and judges, I suspect that this gut-reaction “reason” is likely to prevail for the near future at least. However, the better policy is that post-patent proof that the idea was good is enough. We should go back to the pre-EPC pudding taste test. It will promote innovation and do so better than a rule which precludes post-patent evidence showing the idea works.

### ***What Degree of Plausibility?***

One day that step may be taken. But unless and until it is, the patent must contain some detail making the idea plausible. This leads on to the question of how much detail will do. Lord Sumption’s view is in effect quite a bit: “slimmest evidence” is not enough.<sup>79</sup> There is little logic in this. A man who adds just “slimmest evidence” to human knowledge, has added knowledge, nonetheless. Lord Sumption went as far as to say that Floyd LJ’s statement reduces the requirement of plausibility to “little more than a test of good faith.” Slim evidence is more than mere good faith, however slim it may be. Lord Sumption added: “Indeed if the threshold were as low as he suggests, it would be unlikely to serve even the limited purpose that he assigns to it of barring speculative or armchair claims.” This cannot really be so either. A bare assertion is one thing, an assertion with some additional scientific evidence or reason is more than that. Because there was no issue as to the degree of plausibility before the Supreme Court, Lord Sumption’s view is *obiter dicta* only. It is not binding. Other courts, including lower courts, are free to follow Lord Justice Floyd’s view. Much the stronger view is that they should, not least because the TBA appears to take the same approach as Floyd LJ.<sup>80</sup>

---

<sup>78</sup> Judge O-Malley of the CAFC said much the same as regarding the royalty stacking and hold-up theory in relation to RAND committed patents: “Certainly something more than a general argument that these phenomena are possibilities is necessary, *Eriksson v D-Link* No. 13-1625 (Fed. Cir 2014), p.54.

<sup>79</sup> See above.

<sup>80</sup> See T 184/16 MITSUBISHI. This is a post *Warner-Lambert* TBA decision clearly contrary to Lord Sumption’s view as to the degree of plausibility needed. Since he thought he was following EPO jurisprudence this decision makes it clear there is even less reason for following his more stringent requirement for plausibility. It boils down

### *Sufficiency and Capable of Industrial Application*

One final word. It is about the relationship between “susceptible of industrial application” and sufficiency of description. Part II of the EPC<sup>81</sup> is headed “Substantive Patent Law.” Chapter 1 of Part II is headed “Patentability.” The requirements for grant are just three, that patentable inventions are “new, involve an inventive step and are susceptible of industrial application.”<sup>82</sup> There is no express mention here of an enablement requirement. Nor is there in any of the other provisions of substantive patent law in Part II. Part III of the EPC is headed “The European Patent Application.” It is here than one finds the sufficiency (enablement) requirement. It is Article 83 “Disclosure of the Invention.”<sup>83</sup> The omission of this from Part 2, Chapter 1 is striking. It suggests strongly that sufficiency of description was not regarded as a free-standing requirement. Rather is one aspect of “susceptibility of industrial application.” It does not add to (or detract) from it. That makes sense – if the invention cannot be carried out, it cannot have any application, industrial or not.

If one accepts that, then cases about susceptibility of industrial application are of direct application to the question of a requirement of plausibility. That particularly brings in play *Human Genome Sciences v Eli Lilly*.<sup>84</sup> By the use of bioinformatics the patentee had identified a gene which encoded for what he called neutrokin- $\alpha$ . He took out a patent for that protein and all its millions of antibodies. He did not know what neutrokin- $\alpha$  did in the body or whether it was a good thing or a bad thing. He was able to say from its sequence that it was a bit like some known other proteins. Based on that he speculated about possible therapeutic uses either of neutrokin- $\alpha$  or one or more of its antibodies. That was held to be enough to confer a susceptibility of industrial application. What this shows is that patents can be granted for speculative ideas which have some slight chance of use. The acceptable level of speculation is very high. The same should logically be true for patents for new compounds or second medical use patents.<sup>85</sup>

---

to this: a choice between following his view or that of the TBA. That is not all. It is indeed possible that the whole question of a plausibility requirement may get referred to the Enlarged Board.

<sup>81</sup> Arts. 52-57.

<sup>82</sup> Art. 52(1)

<sup>83</sup> The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

<sup>84</sup> [2011] UKSC 51 in the UK Supreme Court and T0018/09 in the TBA.

<sup>85</sup> Incidentally the fact that Eli Lilly was prepared to invest in their product (an antibody to neutrokin- $\alpha$ ) to the point of phase III trials is an example of a patent not deterring research. Sadly in the end the whole thing came to nothing.