2024:DHC:878-DB

* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

% **Judgment reserved on: 02 November 2023**
Judgment pronounced on: 07 February 2024

\+ **FAO(OS) (COMM) 159/2023 & CM APPL. 39177/2023**

VIFOR (INTERNATIONAL) LIMITED & ANR. .. Appellants

Through: Mr. Neeraj Kishan Kaul, Sr. Adv. with Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Rohin Koolwal, Mr. Hersh Desai, Ms. Ira Mahajan, Ms. Pritha Suri & Mr. Siddhant Chamola, Advs.

versus

MSN LABORATORIES PVT LTD & ANR. ..... Respondents

Through: Mr. G. Nataraj, Mr. Shashikant Yadav, Mr. Rahul B., Advs.
Mr. Chander M. Lall, Sr. Adv. with Mr. Kunal Vajani, Mr. Kunal Mimani, Mr. Shubhang Tandon, Mr. Prashant Alai Advs. for intervener – BDR Pharmaceuticals Pvt. Ltd.

\+ **FAO(OS) (COMM) 160/2023 & CM APPL. 39197/2023**

VIFOR INTERNATIONAL LTD & ANR. ..... Appellants

Through: Mr. Sandeep Sethi, Sr. Adv. with Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Rohin Koolwal, Mr. Hersh Desai & Mr. Siddhant Chamola, Advs.

versus

CORONA REMEDIES PVT LTD & ANR. ..... Respondents

Through: Mr. G. Nataraj, Mr. Shashikant Yadav, Mr. Rahul B., Advs.
Mr. Kunal Vajani, Mr. Kunal Mimani, Mr. Shubhang Tandon,

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Mr. Prashant Alai, Advs. for intervener – BDR Pharmaceuticals Pvt. Ltd.
Ms. Rajeshwari H., Mr. Tahir AJ., Ms. Garima Joshi, Advs.

\+ **FAO(OS) (COMM) 161/2023 and CM APPL. 39201/2023**

VIFOR INTERNATIONAL LTD & ANR. ..... Appellants

Through: Mr. Neeraj Kishan Kaul, Sr. Adv. with Mr. Pravin Anand, Ms. Vaishali Mittal, Mr. Rohin Koolwal, Mr. Hersh Desai, Ms. Ira Mahajan, Ms. Pritha Suri & Mr. Siddhant Chamola, Advs.

versus

DR REDDYS LABORATORIES LTD ..... Respondent

Through: Mr. G. Nataraj, Mr. Shashikant Yadav, Mr. Rahul B., Advs.
Mr. Kunal Vajani, Mr. Kunal Mimani, Mr. Shubhang Tandon, Mr. Prashant Alai, Advs. for intervener – BDR Pharmaceuticals Pvt. Ltd.

CORAM:
HON'BLE MR. JUSTICE YASHWANT VARMA
HON'BLE MR. JUSTICE DHARMESH SHARMA

J U D G M E N T

YASHWANT VARMA, J.

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A. PREFACE/ BRIEF INTRODUCTION

1. These appeals have been preferred against the order dated 24 July 2023 passed by a learned Single Judge disposing of the interim injunction applications made in CS(COMM) Nos. 261/2021, 265/2021, 448/2022 & 450/2022 and refusing interim relief in terms as prayed for by the appellant. The present appeals stand restricted to the aforesaid order insofar as it operates upon CS(COMM) Nos. 261/2021, 265/2021 & 448/2022.

2. The appeals raise an issue of significant import, namely, product-by-process claims and their scope as liable to be construed under the provisions of the **Patent Act, 1970**[1]. The respondents resisted the applications for grant of interlocutory injunction asserting that since the

[1] the Act

claim of the plaintiff/appellant was liable to be construed as a product-by-process claim, it would stand limited to the process alone. It is this principal ground which appears to have found favour with the learned Single Judge while dismissing the prayer for interim relief. The respondents also appear to have urged that the rule of novelty as applicable at the stage of grant would be irrelevant for the purposes of trying infringement allegations and the principles of claim construction alone would govern. The learned Judge has accepted the aforenoted twin submissions as addressed.

3. A reading of the impugned order would indicate that the learned Single Judge firstly found that in all actions alleging infringement, the primary question would be how the claims are to be interpreted and thus discern the scope of the patent. As per the learned Judge it is the claims which would define and be determinative of the allegation of infringement. This will be evident from paragraph 52 of the impugned order which is reproduced hereinbelow:

> "**52.** A reading of Section 10(4)(a) leads to an inevitable conclusion that when a complete specification is filed to describe the invention, it is implicit that the applicant has fully and particularly described not only the invention and its operation but also the use and "method" by which it is to be performed and the monopoly on grant of patent is limited to the scope as defined by the claims. In this context, I may refer to the judgment of the Supreme Court in ***Novartis AG (supra)***, wherein it was emphasized that the scope of monopoly rights granted by means of a patent are in exchange for the disclosure of the invention and the scope cannot travel beyond the disclosure as that would negate the fundamental rule underlying the grant of patent. Relevant passage from ***Novartis AG (supra)*** is as follows:-
>
> > *"118. The submissions of Mr Andhyarujina and Mr Subramanium are based on making a distinction between the coverage or claim in a patent and the disclosure made therein. The submissions on behalf of the appellant can be summed up by saying that the boundary laid out by the claim for coverage is*

> *permissible to be much wider than the disclosure/enablement/teaching in a patent.*
> *119. The dichotomy that is sought to be drawn between coverage or claim on the one hand and disclosure or enablement or teaching in a patent on the other hand, seems to strike at the very root of the rationale of the law of patent.* ***Under the scheme of patent, a monopoly is granted to a private individual in exchange of the invention being made public so that, at the end of the patent term, the invention may belong to the people at large who may be benefited by it.*** *To say that the coverage in a patent might go much beyond the disclosure thus seem to negate the fundamental rule underlying the grant of patents."*
>
> *(emphasis supplied)*

4. Laying emphasis on "claim construction" the learned Judge has made the following pertinent observations:

> **"61**. The next question that posits is 'why claim construction?'. As per Section 10 of the 1970 Act, claims define the scope of the patent and that in turn defines not just the boundaries of coverage of the invention, but also plays a pivotal role in determining the economic value of a patent. The broader the scope of invention, the larger the number of competing products or processes that will infringe the patent and consequently, larger would be its economic value. Subject to other provisions of the 1970 Act, grant of patent under the Act confers upon the patentee the exclusive right to prevent third parties from making, using, selling, importing or offering to sell, without the consent of the patentee, the patented product and where the subject matter of the patent is a process, from using the said process. Therefore, when the patentee sues the alleged infringer, patentee will endeavour to establish that the infringer's product/process is within the scope of the patent of the patentee while the accused infringer will seek to carve out its product/process from the scope of the patented claims. Either way, the decision would have to be predicated on construing the claims and therefore the real challenge for adjudicating the claim of infringement of a patent will be to construe the scope of the claims. In the present case, since Defendants plead non-infringement of IN'536 predicating their case on difference in the respective processes, without prejudice to the argument of invalidity, it becomes imperative to construe the claims of Vifor in order to ascertain the actual scope of the claimed invention."

5. The Court has ultimately and on merits proceeded to record the following conclusions:

> "**105.** Upon a bare perusal of Article 69(1), it is luminously clear that the extent of protection conferred by a patent or a patent application shall be determined by the claims and any *contra* position to state that actual scope of enforcement of the claims of a patent can extend beyond what is defined by the claims, cannot be accepted. Additionally, in the Indian context, the Supreme Court in ***Novartis AG (supra)***, has clearly held that coverage cannot go beyond what is disclosed in the complete specification of the patent application and therefore, the stand adopted in the affidavit, if accepted, would strike at the very root of Indian Patent law. In any event, the applicability of the decision of the UK Supreme Court in ***Actavis v. Lily, [2017] UKSC 48***, which concerned indirect infringement, is yet to be tested in the Indian context. In fact, for the sake of record, it may be noted that in ***Actavis (supra)***, emphasis has been laid on the limitations placed on a claim that a patentee chooses consciously at the time of drafting and filing the claims."

6. Insofar as the subject patent and the nature of product-by-process claim is concerned, the learned Judge has firstly and on facts found that IN'536 was primarily a product-by-process claim. This is evident from the following observations as appearing in paragraph 60:

> "**60.** Coming now to the second issue which directly concerns IN'536. Before moving to claim construction, it would aid to look at definitions in Black's Law Dictionary, 8th Ed., wherein 'product claim' is defined as "*a patent claim that covers the structure, apparatus or composition of a product"* while 'process claim' is defined as "*a patent claim that describes by steps what is done to the subject matter usually a substance in order to achieve a useful result."* 'Product-by-process claim' is defined as "*a patent claim defining a product through the process by which it is made".* It is not Vifor's claim that IN'536 is a process claim. To be categorised as a product claim, a product must be described by its composition and structure, both physical and chemical and not limited by a process. Claim 1 does not fit into the definition of 'product claim' and the limitations on obtaining FCM by a specified process defined in the said claim aligns it with a 'product-by-process claim'. The reasons for this conclusion are adverted to in the later part of the judgment. Insistence of Vifor to treat Claim 1 as a product claim would, in fact, trigger issues of clarity and sufficiency of

disclosure and will be hit by non-compliance of Section 10(5) of the 1970 Act, besides reducing the process terms to a dead letter, even when the process steps are the essence of the claims, both in quantitative and qualitative terms. Be it ingeminated that in an another suit being CS(OS) 1206/2015 filed by Vifor, Court permitted the Defendants to manufacture the water soluble iron carbohydrate complex using a different process which did not infringe the patent of the Plaintiff and this, in my view, recognizes that IN'536 is a product-by-process patent, else the Court would have injuncted the Defendants, since in a product patent the process is irrelevant. Relevant extract of the order dated 16.09.2015 is as follows:

> *"It may be noted that once the plaintiff has a registered patent, defendants cannot use the subject matter of the patent and can only use a process of manufacture which does not infringe the patent of the plaintiff for manufacture of the water-soluble iron carbohydrate complex. It may be noted that learned senior counsel for the defendants states that defendants are not and do not intend to violate the plaintiff's patent and the defendants claim to be using a different process which is not the subject matter of plaintiff's patent."*
>
> *(emphasis supplied)*

7. Drawing from the guiding principles culled out in **F. Hoffmann-La Roche Ltd. & Anr. Vs. Cipla Ltd**.[2], the learned Judge has come to the following conclusion:

> "**67.** Claim 1 thus refers to the product followed by description of the sequence of using aqueous solution of oxidation product of one or more maltodextrins in an alkaline pH in the presence of a specified oxidizing agent i.e. aqueous hypochlorite solution, where the end product i.e. iron carbohydrate complexes have a defined average molecular weight and the limitation to the product by the process is *prima facie* evident. Stand of Vifor that the claim as drafted is a product claim and/or that even with the limitation of the process, the claim leads to a product claim only, would render the description of the claim with a detailed and a specific process meaningless and *otiose*. Therefore, *prima facie* IN'536 is a product-by process claim and monopoly will be limited to the product obtained by the specific process in the claims, going by the first principles delineated in ***F. Hoffmann-La Roche Ltd. & Anr. (supra),*** that claims define the territory or scope of protection."

[2] 2015 SCC OnLine Del 13619

8. While holding against the appellants, the Court also negated the arguments which were addressed on the basis of Claim 1 using the expression *"obtainable from"*. While rendering findings on this aspect, the Court appears to have drawn from the principles enunciated by the High Court of England and Wales in **Hospira UK Limited vs. Genentech Inc.**[3] and other well-known treatise to come to the conclusion that the description of a product by way of a process of manufacture would limit the scope of the patent. The aforesaid view though not explicitly stated, appears to rest on the decision rendered by the United States Court of Appeals for the Federal Circuit in **Atlantic Thermoplastics Co., Inc. V. Faytex Corporation**[4] and **Abbott Laboratories v. Sandoz**[5].

9. The learned Judge had also observed that since iron carbohydrate complexes were already known, the invention forming part of IN'536 resided in the specified process alone. This is evident from the following observations as appearing in paragraph 71 of the impugned decision:

> "**71.** As rightly contended by the Defendants, there is an admission by Vifor that use of iron carbohydrate complexes is known and a water-soluble iron (III) hydroxide sucrose complex is a frequently and successfully used preparation. It is stated that the problem to be solved by the present invention is to provide an iron preparation which is especially to be applied parenterally and can be easily sterilized as the known parenterally applicable preparations on the basis of sucrose and dextran were only stable at temperatures up to 100oC, which made sterilization difficult. It is categorically asseverated in the complete specification that present invention is a process for producing iron carbohydrate complexes wherein one or more 'maltodextrins' are oxidized in an aqueous solution at an alkaline 'pH' using 'aqueous hypochlorite solution' and further

[3] [2014] EWHC 3857 (Pat)
[4] 970 F.2d 834
[5] 566 F.3d 1282

> that when one maltodextrin is applied, the DE value is between 5 and 20 and when mixture of several maltodextrin is applied, the DE value of the mixture lies between 5 and 20 and the DE value of each individual maltodextrin contained in the mixture lies between 2 and 40. Given the admission of Vifor in the complete specification that iron carbohydrate complexes were already known, the only *prima facie* conclusion that this Court can reach is that the purported invention resides in preparing iron carbohydrate complexes with maltodextrin as the starting material and/or the step of oxidation using the specified oxidizing agent i.e. aqueous hypochlorite solution. In fact, what Vifor overlooks in making the submission that the process is inconsequential, is that the characteristic properties that it claims in FCM, distinguished from the prior art, are a direct result of the process used by Vifor, an admission that it makes during the prosecution of the patent application and is glaringly evident in the complete specification. Therefore, the scope of Claim 1 of IN'536 is limited to a product obtained through a specific process feature identified therein and cannot cover any and all processes that may be used by a third party to produce FCM and it is thus held that Claim 1 is a product-by-process claim and not a pure product claim.*"*

10. The Court has also held in favour of the respondents upon finding that they used an oxidizing agent distinct from the one spoken of in the product-by-process claim of the appellant. Presumably, drawing inspiration from the decisions in *Hospira UK Limited*, **Kirin Amgen Inc. & Ors. V. Hoechst Marion Roussel Limited & Ors.**[6], *Atlantic Thermoplastics* and *Abbott Laboratories* the learned Judge came to conclude that the aspect of novelty would be relevant only for the purposes of patentability and not insofar as infringement analysis is concerned. The aforesaid conclusion too is founded on an appreciation of the views as expressed in the aforenoted decisions.

11. At the very outset it becomes pertinent to note that the suit patent expired on 20 October 2023 and thus after we had commenced final hearing on these appeals on 04 September 2023. Parties had continued

[6] [2004] UKHL 46

oral submissions thereafter. However and more importantly and as learned counsels appearing for respective sides urged, the impugned decision represents a significant view taken on product-by-process claims and would have wide ramifications on how such claims are construed by courts in pending and future litigation. Undisputedly, the subject itself has directly arisen for consideration before a court in India for the first time. The judgment assailed before us is also likely to impact the ultimate view that may be taken not only in the suit from which the present appeals emanate but also others which are pending. The appellants had also submitted that the refusal of injunction would also impact their claim for deposit of profits from sales made by the respondents. In our considered opinion, the importance of the issues which were canvassed coupled with the fact that the questions posited requires us, as the first High Court of the country, to enunciate the law with respect to product-by-process claims merits the appeal being considered on merits notwithstanding the expiry of the suit patent. This more so since, and as would be evident from the ultimate conclusions recorded by us, the learned Judge appears to have manifestly erred in enunciating the principles which must govern the interpretation of such claims. There thus exists adequate justification to proceed further upon this appeal.

B. ESSENTIAL FACTS

12. In order to appreciate the challenge which stood raised in the subject suits, we deem it apposite to notice the following essential facts. The appellants claim to be part of the Vifor Pharma Group of Companies founded in 2008 and originally forming part of the erstwhile Galenica Group of Companies established in 1927 in Switzerland. IN’536 is described to be an invention used for

intravenous treatment of iron deficiency and iron deficiency anaemia, when oral iron preparations are rendered ineffective. According to the appellants, **Ferric Carboxymaltose**[7], which is the **International Non-proprietary Name**[8] accorded to the product in dispute, was formulated to meet the requirement of an intravenous iron therapy which would be non-toxic, easily administrable in a variety of clinical conditions and capable of being quickly sterilized. According to the appellants, the preparations in the prior art, and which were based on sucrose and dextran were stable upto temperatures of 100^{o}C which made sterilization difficult. The appellants would contend that there was a necessity to develop an iron preparation which would be free of the noticed adverse effects attached to treatments known in the prior art. FCM which according to the appellants is in a sense a water soluble complex, enables higher dosing of upto 1000 mg iron possible and can be easily administered by way of an intravenous injection within less than 15 minutes. It was the case of the appellants in the suit that IN'536 is a novel water soluble iron carbohydrate complex of iron and oxidation product comprising of one or more maltodextrins.

13. The bibliographic details of IN'536 and which have also been noticed by the learned Judge are extracted hereinbelow:-

Patent Application No.	947/KOLNP/2005
Title of the Invention	Water soluble iron carbohydrate complex and a process for producing water soluble iron carbohydrate complex
Date of Filing	24th May, 2005
International filing date	20th October 2003

[7] FCM
[8] INN

	(filed as PCT/EP2003/011596, published as WO/2004/037865)
Date of publication (Section 11A)	22nd September, 2005
Date of priority	23rd October, 2002 (DE 10249551.1)
Date of grant	25th June, 2008
Date of publication of grant (Section 43)	27th June, 2008
Date of Expiry	20th October 2023

14. The case of the appellant/ plaintiff in the suit was that IN'536 is principally a product claim and which can also be acknowledged as being a product-by-process claim, a practice which is common and well known in claim drafting. They also appear to have placed before the learned Judge detailed figures of sales of FCM in India right from 2017 to 2019. It was their contention that the suit patent has had corresponding counterparts issued in 57 jurisdictions across the globe since its priority date. It was further asserted that neither the suit patent nor any of its foreign counterparts had been successfully assailed in either pre or post grant opposition or in any other legal proceedings. Insofar as the suit patent is concerned it was asserted that the patent had also not been challenged or questioned in pre-grant opposition in India.

15. Undisputedly although the suit patent was applied for in 2003, it came to be granted only in 2008. Regulatory approval to FCM was granted to the second appellant in India in 2011. Although the suit patent has admittedly expired upon completion of its full term of 20 years on 20 October 2023, it was the case of the appellant that they were able to exploit the monopoly flowing from the grant of the suit patent for 12 of its 20 year term. Before the learned Single Judge the

appellants had also placed a tabular statement of the various suits instituted by it to protect IN'536 and the various interim and final orders granted thereon. Those particulars as placed before the learned Single Judge are reproduced hereinbelow:-

S. NO.	PARTICULARS OF THE MATTER	STATUS	ORDER DATE	ORDERS
1.	CS(OS) 2282/2011 VIFOR (INTERNATIONAL) LTD. VS. D. MOHAN RAO & ORS. (SYMED LABS)	Disposed of	16.09.2011	Interim Injunction
			09.09.2015	Disposed of (Undertaking)
2.	CS(OS) 4005/2014 VIFOR (INTERNATIONAL) LTD. VS. MOHAN RAM & ANR. (MAXYCON HEALTH CARE PVT. LTD.) [Later CS(COMM) 712/2018 VIFOR (INTERNATIONAL) LTD. & ANR. VS. MAXYCON HEALTH CARE PRIVATE LIMITED & OTHERS]	Disposed of	22.12.2014	Interim Injunction
			12.04.2018	Decreed (Permanent Injunction and Damages)
3.	CS(OS) 4038/2014 VIFOR (INTERNATIONAL) LTD. VS. NIKUNJ GOSWAMI & ANR.	Disposed of	24.12.2014	Interim Injunction
			03.09.2015	Settlement
4.	CS(OS) 1179/2015 VIFOR	Disposed of	24.12.2014	Interim Injunction

	(INTERNATIONAL) LTD. VS. SURENDER KUMAR TANEJA & ORS. (INTAS PHARMACEUTICALS LTD.)		03.09.2015	Decreed (Permanent Injunction)
5.	CS(OS) 1489/2015 VIFOR (INTERNATIONAL) LTD. VS. SANJAY PATEL & ANR. (NIKSAN PHARMACEUTICAL)	Disposed of	21.05.2015	Interim Injunction
			06.10.2016	Settlement
6.	CS(OS) 1488/2015 VIFOR (INTERNATIONAL) LTD. VS. GAGAN SINGH & ANR. (AVANSCURE PHARMACEUTICALS PRIVATE LIMITED)	Disposed of	21.05.2015	Interim Injunction
			10.04.2018	Decreed (Undertaking)
7.	CS(OS) 4083/2014 VIFOR (INTERNATIONAL) LTD. VS. MR. DHARMENDRA VORA & ANR. (EXIM PHARMA)	Disposed of	29.07.2015	Interim Injunction
			07.11.2017	Decreed (Permanent Injunction and Damages)
8.	CS(COMM) 1548/2016 VIFOR (INTERNATIONAL) LTD. VS. MR. G. SANU NAIR & ORS. (NEOFALCON LIFE SCIENCES AND HEALTH	Disposed of	24.11.2016	Interim Injunction
			18.01.2018	Settlement

	BIOTECH LIMITED)			
9.	FAO(OS) (COMM) 146/2016 VIFOR (INTERNATIONAL) LIMITED VS. UDEET JEEGUL BANKER & ORS. (MANUS AKTEEVA BIOPHARMA)	Disposed of	23.12.2016	Interim Injunction
			12.01.2017	Decreed (Undertaking)
10.	CS(COMM) 214/2017 VIFOR (INTERNATIONAL) LTD. VS. MR. VISHAL N. JAJODIA & ORS. (SWATI SPENTOSE AND ALCON BIOLIFESCIENCES)	Disposed of	21.03.2017	Interim Injunction
			15.09.2017	Settlement
11.	CS(COMM) 417/2017 VIFOR (INTERNATIONAL) LTD. VS. JIGEN BIPINCHANDRA SHAH & ANR. (JIGS CHEMICALS)	Disposed of	31.05.2017	Interim Injunction
			09.05.2018	Interim Injunction
			20.12.2018	Decreed (Undertaking)
12.	CS(OS) 4079/2014 VIFOR (INTERNATIONAL) LTD. VS. SUNILA RAIZADA & ANR. (PUNEET PHARMACEUTICALS)	Disposed of	24.12.2014	Interim Injunction
			23.04.2015	Settlement
13.	CS(COMM) 1680/2016 VIFOR (INTERNATIONAL) LTD. VS. SUVEN	Pending trial ongoing	23.12.2016	Defendant ordered to be bound by the undertaking given under

	LIFE SCIENCES LTD.			S107A of the Patents Act
			19.11.2018	Defendant agreed to be bound by the undertaking dated 23.12.2016 to be continued till the disposal of the suit
14.	CS(COMM) 1206/2015 VIFOR (INTERNATIONAL) LTD. VS. MR. PANKAJ RAMANBHAI PATEL & ANR. (ZYDUS CADILA)	Pending trial ongoing	16.09.2015	Interim Injunction
15.	CS(COMM) 565/2017 VIFOR (INTERNATIONAL) LTD. VS. MANASI MEHTA & ORS. (LA RENON HEALTHCARE)	Pending trial ongoing	31.07.2019 (framing issues)	No injunction order as suit for non-infringement already filed prior to suit for infringement – issues framed and parties directed to expedited trial. Interim Application still pending.
16.	CS(COMM) 261/2021 VIFOR (INTERNATIONAL) LTD. & ANR. VS. MSN LABORATORIES PVT. LTD. & ANR.	Pending recently filed	01.06.2021	Undertaking not to infringe

17.	CS(COMM) 264/2021 VIFOR (INTERNATIONAL) LTD. & ANR. VS. UNIJULES LIFE SCIENCES LTD. & ANR.	Disposed of	02.06.2021	Interim Injunction
			11.03.2022	Settlement
18.	CS(COMM) 265/2021 VIFOR (INTERNATIONAL) LTD. & ANR. VS. DR. REDDY'S LABORATORIES LTD.	Pending recently filed	02.06.2021	Undertaking not to infringe
19.	CS(COMM) 335/2021 VIFOR (INTERNATIONAL) LTD. & ANR. VS. ALEMBIC PHARMACEUTICAL LTD.	Disposed of	28.07.2021	Undertaking not to infringe
			26.11.2021	Settlement
20.	CS(COMM) 210/2022 VIFOR (INTERNATIONAL) LTD. & ANR. VS. HETERO HEALTHCARE LIMITED & ANR.	Pending recently filed	05.04.2022	interim Injunction

16. Insofar as the claims themselves are concerned, it was contended by the appellants that Claim 1 is a product claim for FCM which was merely described by reference to an illustrative process. It was their submission that Claim 1 is an independent product claim while Claims 2 to 6 embody illustrative processes for the making of FCM. It was this stand which was reiterated before us in these appeals with it being

argued that FCM is a new and novel man-made product which was unknown in the prior art.

C. CONTENTIONS OF VIFOR

17. Both Mr. Kaul, learned senior counsel as well as Mr. Anand, learned counsel appearing in support of the appeals had taken us through the claims to drive home their submission that FCM and the claims made in respect thereof clearly answered the description of a product-by-process claim. The appellants also drew our attention to the 'Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals' as formulated by the **Indian Patent Office**[9] to submit that a product-by-process claim is not unknown in the Indian patent system. It was submitted that patentability of a product-by-process claim, as the IPO holds, rests fundamentally on the product itself and is not dependent upon a method of production. Those guidelines, it is pertinent to note also drew strength from an order of the erstwhile **Intellectual Property Appellate Board**[10] which had held that product-by-process claims must define a novel and unobvious product and not be limited by its description in the form of a process. We deem it appropriate to extract the relevant parts of the guidelines hereinbelow:

> **"7.9 Product-by-process claims:**
> A claim to a product obtained or produced by a process is anticipated by any prior disclosure of that particular product per se, regardless of its method of production. In a product-by-process claim, by using only process terms, the applicant seeks rights to a product, not a process. The IPAB held in ORDER No. 200/2012 "…….product-by process claims must also define a novel and unobvious product, and that its patentability cannot depend on the novelty and unobviousness of the process limitations alone. Therefore, the patentability of a product by process claim is based on the product itself if it does not depend on the method of production. In other words, if the product-by-

[9] IPO
[10] IPAB

> process claim is the same as or obvious from a prior product, the claim is un-patentable even if the prior art product was made by a different process. Accordingly the product by process claim must define a novel and unobvious product and the patentability in such claim cannot depend on the novelty and un-obviousness of the process limitation alone". Therefore, in product-by-process claims, the applicant has to show that the product defined in process terms, is not anticipated or rendered obvious by any prior art product. In other words the product must qualify for novelty and inventive step irrespective of the novelty or inventive step of the process*"*

18. In order to appreciate the submissions which were addressed in this respect, we also reproduce the claims as appearing on the record hereinbelow:

> "WE CLAIM
>
> 1. Water soluble iron carbohydrate complexes obtainable from an aqueous solution of iron (111) salt and an aqueous solution of the oxidation product of one or more maltrodextrins using an aqueous hypochlorite solution at a pH-value within the alkaline range, where, when one maltodextrin is applied, its dextrose equivalent lies between 5 and 20, and when a mixture of several maltodextrins is applied, the dextrose equivalent of the mixture lies between 5 and 20 and the dextrose equivalent of each individual maltodextrin contained in the mixture lies between 2 and 40, wherein the obtained iron complexes have an average molecular weight of 80 kDa to 400 kDa.
>
> 2. A process for producing an iron carbohydrate complex as claimed in c1aim 1 wherein one or more maltrodextrins are oxidized in an aqueous solution at an alkaline pH-value using an aqueous hypochlorite solution and the obtained solution is reacted with an aqueous solution of an iron (111) salt, "wherein, when one maltodextrin is applied, its dextrose equivalent lies between 5 and 20, and when a mixture of several maltodextrins is applied, the dextrose equivalent of the mixture lies between 5 and 20 and the dextrose equivalent of each individual maltodextrins contained in the mixtures lies between 2 and 40.
>
> 3. A process as claimed in claim 2, wherein the oxidation of the maltodextrin or the maltodextrins is carried out in the presence of bromide ions.
>
> 4. A process as claimed in claim 2 or 3, wherein the iron (111) chloride is used as the iron (111) salt.
>
> 5. A process as claimed in claims 2, 3 or 4, wherein the oxidized maltrodextrin and the iron (111) salt are mixed to form an

aqueous solution having a pH-value so low that no hydrolysis of the iron (Ill) salt occurs, whereafter the pH is raised to 5 to 12 by the addition of a base.

6. A process as claimed in any of claims 3 to 5, wherein the reaction is carried out at a temperature of 15°C up to boiling point for 15 minutes up to several hours.

7. A medicament containing an aqueous solution of an iron carbohydrate complex as claimed in claim 1 or 2 or obtained in accordance with any of claims 3 to 6.

8. A medicament as claimed in claim 7 formulated for parenteral or oral application.

9. Water-soluble iron carbohydrate complex as claimed in claim 1 for therapy or prophylaxis of iron deficiency."

19. Mr. Kaul learned senior counsel laid emphasis on the fact that the respondents had not assailed the validity of the suit patent before the learned Judge nor had they addressed any submissions which may have cast a cloud on the novelty or inventive step comprised in FCM. It was also submitted that it was on consideration of the novel and inventive attributes of FCM which led to the **World Health Organization**[11] according an INN for the product. It was their contention that INNs' are only allocated to new products and processes. Reliance in this regard was placed on certain authoritative texts, relevant extract whereof are reproduced hereunder:

Guide to EU Pharmaceutical Regulatory Law (7th Edition) – Sally Shorthose

"**[6] Naming the Product**

Choosing an appropriate and acceptable product name is an important precursor to the application process.

The active substance is named according to the INN designated by the World Health Organisation (WHO) or using the relevant chemical name. During clinical trials, the manufacturer applies to the WHO for an INN if the active substance does not already have one. The application form allows the applicant to suggest three names in order of preference (the WHO provides general principles for guidance in devising INNs, based on the use of

[11] WHO

stems). A consultation committee considers the selected names, and the one accepted name is published.

The name of the medicinal product itself may either be a single, 'invented' name (trade name) or a common or scientific name, usually the INN of the active substance (s), accompanied by a trademark or the name of the Marketing Authorisation holder. For applications using the CP, guidance on invented names and the procedure for submitting them for acceptance is available on the EMA website."

Pharmaceuticals Biotechnology and the Law (2nd Edition) – Trevor Cook

"**Non-proprietary names**

14.6 The full chemical name for a medicinal product is usually long and complex and it has been recognised that its use is not desirable for proper communication in medicine and the labelling and promotion of pharmaceuticals. Indeed most biological molecules are of such complexity that they cannot be given a chemical name in the conventional sense. There is thus a need for a relatively simple name by which a particular pharmaceutical is referred to, but one which is not a trade mark, so that for example the drug as sold by others than the original patentee can be identified after patent expiry. Thus the practice has developed of providing drugs with at least two names other than their full chemical name; one, a non-proprietary, or generic, name which is free for all to use in respect of the drug in question and the other a brand name specific to each manufacturer which that manufacturer registers as a trade mark and which he has the exclusive right to use. For example, VIAGRA is Pfizer's trade mark for the erectile dysfunction drug the generic name of the active moiety for which is sildenafil, but the full chemical name for which moiety is 4-[2-ethoxy-5-(4-methy;piperazin-1-yl)sulfonyl-pheyl]-0-methyl-7-propyl-3,5,8,9-tetrazabicyclo [4.3.0] nona-3,7,10-trien-2-one. Sildenafil has other utilities, and thus REVATIO is Pfizer's trade mark for the same active moiety, but as formulated and supplied for the treatment of pulmonary arterial hypertension. Once patent protection for sildenafil expires it will be possible for others to trade in sildenafil not of Pfizer's manufacture, and to call it this, but they will still not be able to use Pfizer's trade marks for it."

Pharmaceutical, Biotechnology, and Chemical Inventions: World Protection and Exploitation (Volume II) - Duncan Bucknell

"**Generic names**

92.6.13 After obtaining a CAS Registry Number, the inventor must apply for a generic name. Multiple organizations standardize generic, non-proprietary drug names through an application process and a naming classification system based on pharmacological or chemical relationships. The American Medical Association (AMA), the United States Pharmacopeial Convention (USP), and the American Pharmacists Association (APhA) co-sponsor the US Adopted Names Council, which assigns a United States Adopted Name (USAN) to pharmaceuticals marketed in the United States. The USAN Council works in conjunction with the International Non-proprietary Name Expert Committee of the World Health Organization (WHO), which assigns an International Non-proprietary Name (INN) globally recognized as public property. The USAN and INN and the USAN designations are considered generic per se and cannot be trade marked or otherwise prohibited from being used by competitors. A proposed USAN may be rejected in view of its similarity to existing trade marks. If a proposed USAN is adopted, it is entered into the USP Pharmacopeia Dictionary of USAN and International Drug Names and the CAS database. In the United States, before a new drug application (NDA) can be filed with the FDA, a USAN is required."

Evergreening Patent Exclusivity in Pharmaceutical Products – Frantzeska Papadopoulou

"**2.3.5. The Name of the Product**

One of the prerequisites for the commercialisation of a pharmaceutical product is being awarded an appropriate name. The name of the active substance will be the international non-proprietary name (INN) designated by the World Health Organization. Thus, if the active substance does not have a name, the product owner should apply for one from the WHO. The applicant should provide three alternatives to be considered by the consultation committee. The chosen name will be published by the WHO. The name of the active substance may be either an invented name or the name of a chemical substance."

20. According to Mr. Kaul, the allotment of an INN to FCM by WHO additionally lends credence to the assertion of the appellant of FCM being a novel product and thus liable to be acknowledged as such, irrespective of the description of one of the possible methods of its production in the claimed document.

21. It was further submitted that an identical challenge to the foreign counterpart of FCM before the **European Patent Office**[12] came to be rejected on 14 September 2016. Our attention was drawn to the following conclusions which were arrived at by the EPO in this respect:

> "The Opposition Division finds that claim 1 as granted does not extend beyond the content of the application as filed. In the original claim 1 from the parental application (D26) the expression "*obtainable from"* is used. This expression shows clearly that the subject-matter of the claim and the application is not only a water-soluble iron–carbohydrate-complexes, which have the same essential features (a weight average molecular weight Mw of 80 kDa to 400 kDa and a ligand from oxidation products from maltodextrin) but can be obtained by other processes. The process as described in general in original claim 1 and the description (from page 2, Line 33 to page 7, Line 7) indeed allows to obtain an oxidized maltodextrin at a depolymerisation degree which finally allows to obtain iron(III)-carbohydrate complexes with an weight average molecular weight Mw of 80 kDa to 400 kDa. For a person skilled in the art it is clear that the oxidation method of the maltodextrin is not decisive when the complex has the molecular weight as defined in granted claim 1. There are further processes which a person skilled in the art might apply that also allow for this, as for instance the so-called "TEMPO process" as cited in the application (see page 3, line 33 to page 4, line 5) and as described in D9. The Opposition Division is thus of the opinion that the expression "*of thus obtained complexed"* on page 7, line 9 does not refer to the entire production process of the complex as described on page4, line 25 to page 7, line 2 in the earlier application (D26) and that the feature "a weight average molecular weight of 80 kDa to 400 kDa) (page 7, lines 9-14) is disclosed separately form this special process and accordingly also separately form the rest of the paragraph (lines 4 to 8). The molecular weight of a compound is clearly a product feature, which characterizes a product and which is not depending on process for production. Even in case that the final product has further features which are depending on the process chosen for maltodextin oxidation directly, it remains that the molecular weight is the indispensable and sufficient feature of the water-soluble iron-oxidized maltodextrin-complex, and that it is thus the essential feature of the invention (see table, comparative examples on page 16). The various product features cited in the paragraph on page 7, lines 4 to 17 do not relate to each other.

[12] EPO

> The process for the production of the complex is not substantial for the invention; the application of the oxidation product of a maltodextrin as lignd and the weight average Mw of the complex are the essential features of the invention (see page, lines 6 to 8, comparative example on page 16, table). Consequently, cancellation of a process feature from claim 1 ("*obtainable from …… involved single maltodextrins at 2 to 40")* and replacement by these two product features ("on basis of oxidation products of maltodextrins" and a weight Mw of the complex of 80 kDa to 400 kDa) does not violate the Guidelines H-V 3.1."

22. Proceeding further along this line the appellants also referred to the examination report drawn by the IPO in the course of the examination process and is dated 10 October 2007 which had cited certain prior arts in support of the objection of lack of novelty and inventive step. Our attention was also drawn to the detailed response dated 19 December 2007 which was submitted by the appellant and which had at that stage itself distinguished each of the cited prior arts on the basis of the novel characteristics of FCM. It was submitted that it was only when the response of the appellants came to be accepted by the IPO that the suit patent came to be granted.

23. Mr. Kaul submitted that under Section 2(1)(j) the Act the word '*invention*' has been defined to mean a *'product'* or a *'process'*. Our attention was also invited to Section 48 of the Act and which confers the right upon a patentee to injunct infringers both in respect of a patented product or process. It was the submission of learned senior counsel that a product-by-process is essentially a product claim drafted in a particular style and on account of the difficulty of describing large molecules. It was submitted that notwithstanding the product having been described in fuller detail in process terms, the same would not detract from the product itself being novel and unobvious. It was submitted that product-by-process claims when found to be directed to

a product per se would confer a monopoly not merely on the process as disclosed but on the product itself. It was submitted that the guidelines framed in this respect and alluded to hereinabove follow a position identical to that of the EPO and which would be evident from the following guidelines of the EPO:

> "**4.12 Product-by-process claim**
> A claim defining a product in terms of a process is to be construed as a claim to the product as such. The technical content of the invention lies not in the process *per se*, but rather in the technical properties imparted to the product by the process. Claims defining plants or animals produced by a method including a technical step which imparts a technical feature to a product constitute an exception in so far as the requirements of Art. 53(b) as interpreted by Rule 28(2) are concerned. The exclusion under Rule 28(2) regarding plants and animals exclusively obtained by means of an essentially biological process does not apply to patents granted before 1 July 2017 nor to pending patent applications with a filing date and/or a priority date before 1 July 2017.
> If a technical feature of a claimed plant or animal, e.g. a single nucleotide exchange in the genome, can be the result of both a technical intervention (e.g. directed mutagenesis) and an essentially biological process (a natural allele), a disclaimer is necessary to delimit the claimed subject-matter to the technically produced product (see examples in G-II, 5.4.2.1 and G-II, 5.4). If, on the other hand, the feature in question can unambiguously be obtained by technical intervention only, e.g. a transgene, no disclaimer is necessary. For the general principles governing disclaimers see H-V, 4.1 and H-V, 4.2.
> If the process through which the claimed plant or animal is defined does not impart identifiable and unambiguous technical features to the plant or animal, e.g. the genetic information present in the genome, the claim directed to a plant or animal lacks clarity.
> Claims for products defined in terms of a process of manufacture are allowable only if the products as such fulfil the requirements for patentability, ineralia that they are new and inventive, and it is impossible to define the claimed product other than in terms of a process of manufacture. A product is not rendered novel merely by the fact that it is produced by means of a new process. The claim may for instance take the form "Product X obtainable by process Y". Irrespective of whether the term "obtainable", "obtained", "directly obtained" or an equivalent wording is used in the product-by-process claim, it is

> still directed to the product *per se* and confers absolute protection upon the product.
> As regards novelty, when a product is defined by its method of manufacture, the question to be answered is whether the product under consideration is identical to known products. The burden of proof for an allegedly distinguishing "product-by-process" feature lies with the applicant, who has to provide evidence that the modification of the process parameters results in another product, for example by showing that distinct differences exist in the properties of the products. Nevertheless, the division needs to furnish reasoned argumentation to support the alleged lack of novelty of a product-by-process claim, especially if this objection is contested by the applicant."

24. It was submitted that the overarching aspect of patentability even if they be placed as product-by-process claims has been universally acknowledged and accepted right from the time when the EPO rendered its decision in **International Flavors & Fragrance Inc.**[13] Reliance was placed on the following passages from that decision:

> "7. Inventions fall either into the category of products, e.g. articles, devices or materials, or of processes, e.g. methods of preparing a product, or using an article, or obtaining a result. Nevertheless, the invention defined in the claims for products or for processes must all be novel, inventive and industrially applicable according to Article 52(1). Whilst a process may well be novel and deserves full protection in view of its inventiveness, the same may not be true for its product if that is known or obvious in the light of the state of the art. Notwithstanding this, the special protection provided by Article 64 (2) EPC extends even to products which are not themselves inventions. According to the submissions of the appellants, the protection provided by "product-by-process" claims should go beyond the limits of "direct products" in Article 64(2) and ought to be equal to that enjoyed by products which are claimed per se, with no restriction to the details of their preparation. This, irrespective of the fact that the product protected in this manner may not represent an invention at all, as such.
>
> 8. The Guidelines for Examination in the EPO (C.III. 4.7b) allows claims for products defined in terms of a process of manufacture provided the products themselves fulfil the requirements for patentability. This may well be the only way to define certain natural products or macromolecular materials, of

[13] (1984) O.J. EPO 309

unidentified or complex composition which have not yet been defined structurally. Nevertheless, before such claims are allowable their patentability as products must be established since such definition is in lieu of the normal definition by structure.

9. The appellants referred to German law in this respect and alleged that product-by-process claims had also been validly granted in cases where the product itself was not patentable. The evidence submitted in this respect by Dr. Goddar refers to Benkard 7. Ed. page 353 and 355. It is clear that the statements there relate to the question of direct product protection for processes under §9(2)(3) of the Patent Law which is analogous to Article 64(2) EPC. It is apparent that the submitted Opinion is silent about the more relevant entries in the same textbook (e.g. Benkard, 7. Ed. §1.14 on page 124, 86 on pages 158 and 159, and 88(dc) on page 159) where it is clearly indicated that a claim to a patentable product is allowable as long as neither the structure nor the physical characteristics of the material are known. This is based on the appropriate decisions of the Supreme Court and the Federal Patent Court ("Trioxan" B1PMZ, 1971, 73, pp. 374-33; BPatGE-20, pp. 20-25, 1 BGHZ 57,1.). There is no suggestion in the attached documents that unpatentable products could be expressly claimed in this manner.

10. An earlier decision of the Board already established that "the effect of a process manifests itself in the result, i.e. in the product in chemical cases, together with all its internal characteristics and the consequence of its origin, e.g. quality, yield and economic value". ("Gelation/Exxon" T 119/82, 12.12.1983). Although problems may be recognised in processes known in the state of the art which are then removed by appropriate modifications or by an altogether different approach, the effect of such measures en route ultimately manifests itself in the technical and economic characteristics of the product, the real purpose of the exercise. Whilst some features of such end-effects may be drawn into the definition of the process for reasons of clarity and of conciseness, the product is in consequence of the invention, without being the invention itself, which is rather the novel interaction represented by the process in such cases. Any attempt to claim the in itself non-inventive product by means of product-by-process claims is claiming the mere effects instead. Whilst reliance on the provisions on Article 64(2) EPC may nevertheless provide protection beyond the invention in processes leading to known or patentable products alike, this should not be afforded for both kinds of product themselves on the same footing, irrespective of their character. This must therefore be rejected as unjustified and

> contrary to the requirements of Article 52 (1) and 84 EPC. The Board takes the view that in order to minimise uncertainty, the form for a claim to a patentable product as such defined in terms of a process of manufacture (i.e. "product-by- process claims"), should be reserved for cases where the product cannot be satisfactorily defined by reference to its composition, structure or some other test- able parameters.
>
> 11. The Board has seriously considered the well known fact that both "omnibus" and "product-by-process" claims were commonly admitted in the United Kingdom, one of the member states of the Convention. Nevertheless, it is also important to note that in no other member state have they gained acceptance beyond a manner of claiming structurally undefinable product inventions, and there appears to be no room under the Articles or Rules of the Convention to admit such claims on the basis of practice in a single Contracting State. Since the appeal is unsuccessful as regards the issues under con- sideration, the refund of the appeal fee must be rejected."

25. Mr. Kaul further submitted that a selective and partial consideration of the decisions rendered by the House of Lords in *Kirin Amgen,* and the High Court of England and Wales in *Hospira UK Limited* has led the learned Judge to erroneously hold that product-by-process claims were recognized or held to be limited by process terms. Mr. Kaul submitted that the learned Judge failed to appreciate the observations as rendered in *Kirin Amgen* wherein it was held that where a product is identical to one which is known, the mere adoption of a new process of manufacture would not confer novelty on it. It was submitted that the House of Lords had clearly held that if a product were known and not novel it would clearly not be entitled to patent protection. It was submitted that the learned Judge also failed to appreciate the accepted distinction which is recognized to exist between the phrases "obtained by" on the one hand and "obtainable by" or "obtainable from" and which was even acknowledged in *Kirin Amgen* and *Hospira UK Limited*. It was submitted that the conclusion

ultimately arrived at by the learned Judge also failed to bear in mind that in both *Kirin Amgen* and *Hospira UK Limited.* the product in question were already known in the prior art. This was submitted in the context of the erythropoietin hormone in *Kirin Amgen* being found to be naturally occurring and Trastuzumab in *Hospira UK Limited* being already known. It is in the aforesaid backdrop that Mr. Kaul had urged that the learned Judge has clearly erred in holding that product-by-process claims have been held to be limited by process terms in the decision of *Kirin Amgen* and *Hospira UK Limited.*

26. It was then submitted that the aspect of limitation and which appears to have found favour with the learned Judge essentially flows from the findings returned by the majority in *Abbott Laboratories*. The decision of the Federal Court was assailed and criticized on various grounds. It was firstly submitted that the holding in **Scripps Clinic Research Foundation vs. Genentech Inc Scripps Clinic & Research Foundation**[14] had held the field till it came to be departed from in *Atlantic Thermoplastics*. It was submitted that the learned Judge has rested her conclusions relating to the scope and ambit of product-by-process claims on an *en banc* ruling of a divided Federal Court. It was submitted that out of a Bench comprising of eleven justices, a scathing minority opinion came to be penned by three members of the Bench. It was urged that a reading of the minority opinion would unerringly point towards the *en banc* Court ignoring settled and binding precedent. It was the submission of Mr. Kaul that the *en banc* Court ruling in *Abbott Laboratories* had overruled a century worth of precedent and propounded a novel rule of process terms acting as limitations when

[14] 927 F.2d 1565

viewed in the context of infringement actions. According to Mr. Kaul if patentability be an inviolable feature of a valid patent granted under the Act, there would exist no justification to draw a distinction between patentability and infringement. According to learned senior counsel, the test of invention and novelty would apply with equal force to both actions, namely, a challenge to validity as well as one for infringement.

27. The primary challenge which the appellants raised against the impugned order was also based on the assertion that the learned Single Judge had visibly failed to either notice or deal with its submissions relating to the novelty of FCM and the inventive qualities of that product especially when the same had never been questioned or assailed by the respondents. It was submitted by Mr. Kaul that in the entire judgment the learned Single Judge has abjectly failed to consider whether FCM was known in the prior art. It was submitted that quite apart from the fact that a dispute in that respect having never been raised by the respondents, the prior art which was cited on their behalf in the three suits carried no whisper of FCM. Reliance in this respect was also sought to be placed upon what was ascribed to be a clear admission on the part of MSN Laboratories and as reflected from the recordal of facts by the learned Judge in para 21:-

> "**21.** By virtue of provision of Section 48 of the 1970 Act, upon grant of IN'536, Vifor has acquired exclusive right to prevent third parties, who do not have its consent, from using, making, offering for sale or importing and selling the product FCM, which is protected by IN'536 or the product obtained directly from the process protected by IN'536 in India. FCM is a product covered directly under IN'536 and has definite and unique characteristic features, such as average molecular weight between 80 kDa and 400 kDa and manufacture by any unauthorized entity of a product which exhibits the same characteristics, would amount to infringement of IN'536, by virtue of Section 48 of the 1970 Act. Defendant No.1/MSN in CS(COMM) 261/2021 is manufacturing the product FCM

> protected by IN'536, which is evident from its Patent Application No.201841012945. MSN's patent application mentions US patent corresponding to IN'536 as the earliest literature where FCM was disclosed and MSN has also sought approval from Indian Authorities for building capacity to manufacture large quantities of FCM. Evidently, this is being undertaken with the aim of launching an infringing version of FCM in the near future, *albeit* Vifor has already filed pre-grant opposition to the patent application of MSN. As can be seen from the website of the Defendant, MSN's product under the brand FEINJ is FCM, a water-soluble iron carbohydrate complex with a molecular weight of approximately 150 kDa, which is between 80 kDa and 400 kDa."

28. It was pointed out by learned counsels that MSN Laboratories had throughout conceded and admitted to manufacturing FCM, a fact which is evident from its own patent application. It was submitted that the said patent application itself referred to the US patent corresponding to IN'536 as the earliest literature where FCM was disclosed. It was submitted that the learned Single Judge has committed a manifest illegality in proceeding on the basis that the invention resided in the use of iron carbohydrate complexes which were already known. Our attention was specifically drawn to para 71 in this respect. Both Mr. Kaul and Mr. Anand vehemently submitted that iron carbohydrate complexes are not FCM. It was their submission that similarly hydroxide sucrose complexes are also not FCM. It was their contention that the learned Single Judge failed to bear in mind that the invention was claimed in FCM which was undisputedly a novel product and which had ultimately led to it being accorded an INN. It was submitted that FCM is a complex macromolecule capable of being described only by the way in which it was made. It was the contention of the appellant that a reading of the claims would indicate that the invention was a water-soluble iron carbohydrate complex having the following essential

features: (a) an iron (III) core; (b) an oxidized maltodextrin as ligand; and (c) average molecular weight in the range of 80-400 kDa.

29. We were apprised that the priority application in respect of the suit patent was filed on 23 October 2002. This was followed by the filing of the **Patent Cooperation Treaty**[15] application on 20 October 2003. It was submitted that while the appellant was conscious of the invention of a new product, on the date when it filed its patent application, it was impossible for it to describe the product without referring to the process used for its manufacture. However, according to the appellant, this would clearly not diminish from FCM being accepted and acknowledged as a product per se. For the purposes of novelty, reliance was also placed on the International Preliminary Examination Report drawn by the **World Intellectual Property Organization**[16] the relevant extract whereof reads as follows:

> "In light of the documents cited in the international search report, it is considered that the invention as defined in the claims meets the criteria mentioned in Article 33(1) PCT, i.e., it appears to be novel and to involve an inventive step."

30. It was submitted that it was only thereafter that the appellant commenced clinical trials and approached the WHO for the assignment of an INN. The INN FCM was thereafter assigned to the appellants in March 2008. Without prejudice to the above, the appellants submitted that the stand as struck by the respondents is clearly contradictory when one views the information of MSN Laboratories which itself acknowledges and admits that the product proposed to be manufactured by it was a FCM injection. It was additionally pointed out that the patent application of MSN Laboratories itself not only discloses that its

[15] PCT
[16] WIPO

proposed product was FCM an iron replacement product in para 10, it also makes an unabashed reference to the corresponding US patent of the appellant being US patent no. 7612109 B2. Paras 10 and 25 of MSN Laboratories' patent application are reproduced hereunder:

> "**10.** Ferric carboxymaltose, an iron replacement product, is an iron carbohydrate complex with the chemical name of polynuclear iron (III) hydroxide 4(R)-(poly-(1-4)-*O*- -*a*-D-glucopyranosyl)-oxy-2(R),3(S),5(R),6-tetrahydroxy-hexanoate. The relative molecular weight is approximately 150 000 Da.
>
> **xxxx xxxx xxxx**
>
> **25.** US Patent No. 7612109 B2 herein after referred as "US'109" discloses Water-soluble iron carbohydrate complexes (ferric carboxymaltose complexes) obtainable from an aqueous solution of an iron (III) salt, preferably iron (III) chloride, and an aqueous solution of the oxidation product of one or more maltodextrins using an aqueous hypochlorite solution."

31. The appellants on facts also questioned the stand of the respondents who had contended that since they were using a different oxidising agent the allegation of infringement would not be made out. It was submitted in this regard that the respondents have sought to incorrectly convey the impression that the use of an oxidising agent was the inventive characteristic of FCM. This according to the appellants is a submission addressed in ignorance of Claim 1 using the expression "obtainable from". Our attention was also drawn to line 25 of the specifications of the suit patent where the appellant had clearly accepted and acknowledged that it would be possible to use any other oxidation system. It was in the aforesaid backdrop that learned counsels argued that the mere tweaking of the manufacturing process and substituting the oxidising agent would not absolve the respondents from the allegation of infringement.

32. The appellants also questioned the arguments advanced by the respondents and revolving around the DE value of FCM. It was pointed out that some of the respondents had urged that since the DE value of maltodextrin had been clearly specified, a product which obtained a DE value outside the range defined by the appellant would constitute evidence of the product not being infringing. It was pointed out to us that Corona Remedies had admitted that they used starched hydrolysis products with a DE value of 25-27 as the carbohydrate ligand and not oxidized maltodextrins. It was on this basis that Corona Remedies had claimed that their final product would not fall within the scope of Claim 1 of the suit patent. It was submitted that if this position were treated to be correct then Corona Remedies could not possibly title its product as being FCM.

33. We were informed that the appellants had placed voluminous technical literature before the learned Single Judge and which had established that maltodextrins could have a DE value upto 96. It was submitted that Claim 1 of the suit patent itself had spoken of maltodextrins of upto a DE value of 40 being possible. It was in the aforesaid backdrop that Mr. Kaul contended that the learned Judge has clearly erred in proceeding on the premise that maltodextrins with a DE value range of 2-20 was an essential facet of the process of manufacturing FCM. The findings in this respect were additionally assailed on the basis of the U.S. Markman Hearing order in which maltodextrins were accepted as being unbound by a DE value limitation. The relevant extracts of the aforesaid order are reproduced hereinbelow:

> **"IT IS** this 28th day of June, 2021, **ORDERED** and **DECLARED** that the Disputed Claim Terms are construed as follows:

Disputed Claim Term	Construction
"maltodextrin"	"a mixture of saccharides of variable length composed of chains of D-glucose units connected primarily by α (1→4) glycosidic bonds"

34. The principal bone of contention before the learned Single Judge clearly appears to have been the scope and extent of product-by-process claims and the principles deducible from the decisions in *Kirin Amgen, Hospira UK Limited* and *Abbott Laboratories*. Insofar as *Abbott Laboratories* is concerned while the respondents sought to draw sustenance from the judgment rendered by the majority of the Court, the appellants had commended for the consideration of the learned Single Judge the view as expressed by the minority. The reliance on the aforenoted foreign precedents appears to have been driven by the absence of any precedent rendered by Courts in India on the scope of product-by-process claims.

35. Before proceeding to notice the passages of *Kirin Amgen*, which were relied upon by the appellants, it is relevant to note that the said decision pertained to a European patent relating to the production of erythropoietin by use of recombinant DNA technology. Erythropoietin, as would be evident from a reading of the decision in *Kirin Amgen,* was identified as a hormone synthesized naturally in human kidneys. The product was thus known and found in nature. The appellants would contend that *Kirin Amgen* was thus a decision which was concerned with the process of making erythropoietin artificially for use as a drug. While dealing with the extent of protection conferred on a patentee and claim construction, Lord Hoffmann delivering the speech on behalf of

the House of Lords enunciated the legal position in the following terms:-

> "**18.** Until the Patents Act 1977, which gave effect to the European Patent Convention ("EPC") there was nothing in any UK statute about the extent of protection conferred by a patent. It was governed by the common law, the terms of the royal grant and general principles of construction. It was these principles which Lord Diplock expounded in the leading case of *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, which concerned a patent granted before 1977. But the EPC and the Act deal expressly with the matter in some detail. Article 84 specifies the role of the claims in an application to the European Patent Office for a European patent:
>
> > "The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description."
>
> **19.** For present purposes, the most important provision is article 69 of the EPC, which applies to infringement proceedings in the domestic courts of all Contracting States:
>
> > "The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims."
>
> **20.** In stating unequivocally that the extent of protection shall be "determined" (in German, "*bestimmt*") by the "terms of the claims" (*den Inhalt der Patentansprüche*) the Convention followed what had long been the law in the United Kingdom. During the course of the 18th and 19th centuries, practice and common law had come to distinguish between the part of the specification in which the patentee discharged his duty to disclose the best way of performing the invention and the section which delimited the scope of the monopoly which he claimed: see Fletcher-Moulton L J in *British United Shoe Machinery Co Ltd v A. Fussell & Sons Ltd* (1908) 25 RPC 631, 650. The best-known statement of the status of the claims in UK law is by Lord Russell of Killowen in *Electric and Musical Industries Ltd v Lissen Ltd* (1938) 56 RPC 23, 39:
>
> > "The function of the claims is to define clearly and with precision the monopoly claimed, so that others may know the exact boundary of the area within which they will be trespassers. Their primary object is to limit and not to extend the monopoly. What is not claimed is disclaimed. The claims must undoubtedly be read as part of the entire

document and not as a separate document; but the forbidden field must be found in the language of the claims and not elsewhere."

xxxx xxxx xxxx

32. Construction, whether of a patent or any other document, is of course not directly concerned with what the author meant to say. There is no window into the mind of the patentee or the author of any other document. Construction is objective in the sense that it is concerned with what a reasonable person to whom the utterance was addressed would have understood the author to be using the words to mean. Notice, however, that it is not, as is sometimes said, "the meaning of the words the author used", but rather what the notional addressee would have understood the *author* to mean by using those words. The meaning of words is a matter of convention, governed by rules, which can be found in dictionaries and grammars. What the author would have been understood to mean by using those words is not simply a matter of rules. It is highly sensitive to the context of and background to the particular utterance. It depends not only upon the words the author has chosen but also upon the identity of the audience he is taken to have been addressing and the knowledge and assumptions which one attributes to that audience. I have discussed these questions at some length in *Mannai Investment Co Ltd v Eagle Star Life Assurance Co Ltd* [1997] AC 749 and *Investors Compensation Scheme Ltd v West Bromwich Building Society* MANU/UKHL/0054/1997 : [1998] 1 WLR 896.

33. In the case of a patent specification, the notional addressee is the person skilled in the art. He (or, I say once and for all, she) comes to a reading of the specification with common general knowledge of the art. And he reads the specification on the assumption that its purpose is to both to describe and to demarcate an invention - a practical idea which the patentee has had for a new product or process - and not to be a textbook in mathematics or chemistry or a shopping list of chemicals or hardware. It is this insight which lies at the heart of "purposive construction". If Lord Diplock did not invent the expression, he certainly gave it wide currency in the law. But there is, I think, a tendency to regard it as a vague description of some kind of divination which mysteriously penetrates beneath the language of the specification. Lord Diplock was in my opinion being much more specific and his intention was to point out that a person may be taken to mean something different when he uses words for one purpose from what he would be taken to mean if he was using them for another. The example in the *Catnic* case was the difference between what a person would reasonably be taken to mean by using the word "vertical" in a mathematical

theorem and by using it in a claimed definition of a lintel for use in the building trade. The only point on which I would question the otherwise admirable summary of the law on infringement in the judgment of Jacob L J in *Rockwater Ltd v Technip France SA* (unreported) [2004] EWCA Civ 381, at paragraph 41, is when he says in sub-paragraph (e) that to be "fair to the patentee" one must use "the widest purpose consistent with his teaching". This, as it seems to me, is to confuse the *purpose* of the utterance with what it would be understood to *mean*. The purpose of a patent specification, as I have said, is no more nor less than to communicate the idea of an invention. An appreciation of that purpose is part of the material which one uses to ascertain the meaning. But purpose and meaning are different. If, when speaking of the widest purpose, Jacob L J meant the widest meaning, I would respectfully disagree. There is no presumption about the width of the claims. A patent may, for one reason or another, claim less than it teaches or enables.

34. "Purposive construction" does not mean that one is extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims. The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made. On the other hand, it must be recognised that the patentee is trying to describe something which, at any rate in his opinion, is new; which has not existed before and of which there may be no generally accepted definition. There will be occasions upon which it will be obvious to the skilled man that the patentee must in some respect have departed from conventional use of language or included in his description of the invention some element which he did not mean to be essential. But one would not expect that to happen very often."

36. Proceeding to deal with product-by-process claims, Lord Hoffmann made the following pertinent observations:

"**80.** I do not dispute that a claim may, upon its proper

construction, cover products or processes which involve the use of technology unknown at the time the claim was drafted. The question is whether the person skilled in the art would understand the description in a way which was sufficiently general to include the new technology. There is no difficulty in principle about construing general terms to include embodiments which were unknown at the time the document was written. One frequently does that in construing legislation, for example, by construing "carriage" in a 19th century statute to include a motor car. In such cases it is particularly important not to be too literal. It may be clear from the language, context and background that the patentee intended to refer in general terms to, for example, every way of achieving a certain result, even though he has used language which is in some respects inappropriate in relation to a new way of achieving that result: compare *Regina (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687. In the present case, however, I agree with the Court of Appeal (and with the judge, before he came to apply the Protocol questions) that the man skilled in the art would not have understood the claim as sufficiently general to include gene activation. He would have understood it to be limited to the expression of an exogenous DNA sequence which coded for EPO.

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86. TKT appeals against the rejection by both the judge and the Court of Appeal of its challenge to claim 26 on the ground of anticipation. This raises a point of principle about what counts as a new product."

87. Section 1(1)(a) of the Act says that a patent may be granted only for an invention which is new and section 2(1) says that an invention shall be taken to be new if it does not form part of the state of the art. The Act assumes that any invention will be either a product or a process (see the definition of infringement in section 60.) Claim 26 is to a product, namely a polypeptide which is the expression in a host cell of a DNA sequence in accordance with claim 1. Such a product is EPO and the question is whether it is new or the same as the EPO which was already part of the state of the art, namely the uEPO which Miyake and others had purified from urine.

88. The practice in the United Kingdom under the Patents Act 1949 and earlier was to treat the fact that a product was made by a new process as sufficient to distinguish it from an identical product which was already part of the state of the art. This was not particularly logical, because the history of how a product was made is not an attribute which it carries around and makes it something new. It was still the same product, even if made in a

different way. But the English practice had practical advantages when the extent of protection conferred by a patent was undefined (as it was until 1977) and it was assumed that a process claim could be infringed only by using that process in the United Kingdom. A product-by-process claim had the advantage of enabling the inventor of a new process to pursue not only the manufacturer who infringed his claim to the process but also, by virtue of the separate "product-by-process" claim, anyone who dealt in a product which had been made by that process. That was particularly useful in the case of the importation of a product made by someone outside the jurisdiction by a process which would have infringed the process claim if it had been made in this country.

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90. This provision largely removes the practical argument for allowing product-by-process claims. The European Patent Office has therefore been able to accept the logical argument that a new process is not enough to make the product new. It will not ordinarily accept a "product-by-process" claim. A patentee who wishes to complain of dealings in a product made by his patented process must rely on his process claim and article 64(2). The principle is clearly stated by the Technical Board of Appeal in *International Flavors & Fragrances Inc* [1984] OJ EPO 309, in which the United Kingdom was singled out as the only Member State of the EPC which accepted product-by-process claims.

91. The only case in which the EPO will accept a claim to a product defined in terms of its process of manufacture is when the product is new in the sense of being different from any existing product in the state of the art but the difference cannot be described in chemical or physical terms. As the Board said in *International Flavors* (at paragraph 8):

> "This may well be the only way to define certain natural products or macromolecular materials of unidentified or complex composition which have not yet been defined structurally."

37. On noticing the ultimate findings rendered by the Court of Appeals, Lord Hoffmann found as under:

> "**97.** Both the judge and the Court of Appeal rejected this argument as a matter of law, and for similar reasons. In the Court of Appeal, Aldous LJ said:
>
> > "The [Technical] Board [of the EPO] accepted that it is permissible to have a claim to a product defined in terms

> of a process of manufacture, but state that such claims should only be granted in cases when the product cannot be satisfactorily defined by reference to its composition, structure or other testable parameter. That is a rule of practice which is not the concern of the national courts."
>
> **98.** That is, I must respectfully say, an incomplete statement of the position of the Board. The first requirement is that the product must be new and that a difference in the method of manufacturing an identical product does not make it new. It is only if the product is different but the difference cannot in practice be satisfactorily defined by reference to its composition etc that a definition by process of manufacture is allowed. The latter may be a rule of practice but the proposition that an identical product made by a new process does not count as new is in my opinion a proposition of law. It cannot be new in law but not new for the purposes of the practice of the Office."

38. The cause before the House of Lords was ultimately disposed of in the following terms:

> "**99.** Aldous L J then went on to say "it seems that the Office concluded that claim 26 fell within the type of case where the product could not be satisfactorily defined by its features." That is true, but again incomplete. The important point is that the Office found that rEPO according to claim 26 was a new product because its glycosolation pattern would necessarily be different from that of uEPO. Once this finding of fact was removed, there was no basis for allowing claim 26.
>
> **100.** Aldous L J also relied upon article 64(2) as being consistent with a product-by-process claim. But in my opinion it leads to exactly the opposite conclusion and the Technical Board in *International Flavors* so held. The point of article 64(2) is to extend the protection afforded by a process claim to a product directly made by that process and to make it unnecessary to claim the product defined by reference to the process.
>
> **101.** I think it is important that the United Kingdom should apply the same law as the EPO and the other Member States when deciding what counts as new for the purposes of the EPC: compare *Merrell Dow Pharmaceuticals Inc v H.N. Norton & Co Ltd* [1996] RPC 76, 82. It is true that this means a change in a practice which has existed for many years. But the difference is unlikely to be of great practical importance because a patentee can rely instead on the process claim and article 64(2). It would be most unfortunate if we were to uphold the validity of a patent which would on identical facts have been revoked in opposition proceedings in the EPO. I would therefore allow this part of the

> appeal and declare claim 26 invalid on the ground of anticipation."

39. Both Mr. Kaul and Mr. Anand thus submitted that *Kirin Amgen* attuned the position of law as prevailing in England with that as existing under the EPO while significantly observing that a product-by-process patent would under the English law be entitled to protection of the product itself where it is found to be novel or new and in cases where the inventive attributes of the product cannot satisfactorily be defined except by reference to a process of manufacture.

40. Post the decision handed down by the House of Lords in *Kirin Amgen*, the question of construction of product-by-process claims again arose for consideration of the Patents Court in the High Court of Justice Chancery Division of the UK in *Hospira UK Limited*. Mr. Kaul and Mr. Anand firstly pointed out that *Hospira UK Limited* was principally concerned with the product Trastuzumab, which was already known. This according to learned counsel is evident from a reading of paragraphs 5 and 6 of that decision which are reproduced hereinbelow:

> "**5.** Trastuzumab itself is protected by a different patent, EP (UK) 0 590 058 and supplementary protection certificate SPC/GB04/015. That SPC expired on 29th July 2014. Hospira wishes to sell generic trastuzumab now that the SPC has expired. Hospira needs a generic authorisation based on the existing marketing authorisation for Herceptin and argued that the regulatory framework applicable to such biosimilar products at least strongly encourages, if it does not actually require, the generic to use the same formulation as the originator's product. This action is to clear the way.
>
> **6.** Trastuzumab and rhuMAb E25 are monoclonal antibodies. Monoclonal antibodies are large protein molecules. Although by 1996 the pharmaceutical industry had had a long history of formulating small molecule drugs, the formulation of therapeutic proteins in general and antibodies in particular was not so well established. This is an important factor in this case."

41. The Court in *Hospira UK Limited* while dealing with the subject of product-by-process claims observed as follows:

> "**125.** Product by process claims are tricky. Before coming to the House of Lords in ***Kirin Amgen*** there are some background matters to deal with.
>
> **126.** One of the key problems which a system of patents for inventions has to handle is how to legislate for future inventive (non-obvious) developments. By definition they are often hard to foresee. One way this is done is to give inventors more or less complete freedom in the drafting of their patent applications. They can define the invention in a claim in any way and using any language they like so long as the definition is clear to a person skilled in the art and the invention satisfies various other criteria.
>
> **127.** Most inventions are either products or processes and it has proved possible for the law to define acts of infringement by reference to these different kinds of inventions. Section 60 of the Patents Act 1977 does just this. It is based on the Community Patent Convention (CPC) rather than the EPC. The way s60(1) is drafted one might assume that an invention must be either a product or a process. There is no such rule. By and large the system works but there can be difficulties. A well known example is a new pharmaceutical use of an old drug which gives rise to Swiss style claims. Infringement of these claims is often argued only under s60(2) (infringement by supplying means essential) which avoids the problem of deciding whether it is a product or a process.
>
> **128.** Another kind of claim which straddles the boundary between products and processes is a product by process claim. As a matter of language there are two kinds: (1) a product "obtained by" a process, and (2) a product "obtainable by" a process. At least at first sight they are different."

42. The Court in *Hospira UK Limited* also had an occasion to consider contentions addressed and revolving around the meaning to be assigned to the phrases "obtained by" and "obtainable from". While dealing with the former, it significantly observed as under:-

> "**129.** At first sight the scope of a claim to a product "obtained by" a process would be only to products which had actually been made by the process. There might be problems of proof in an infringement case or for novelty but conceptually there is no difficulty. If no products had ever been made that way in the

> past, then the claim would be novel. The fact that such products are physically entirely identical to products made in the past would not alter the fact that no product made by that process had been made available to the public before. They would only be infringed by products actually made by the relevant process. This was the view taken of product by process claims in the Court of Appeal in ***Kirin Amgen*** ([2002] EWCA Civ 1096, [2003] RPC 3)."

43. Turning then to the meaning to be ascribed to the expression "obtainable by", the Court held:-

> "**131.** Turning to "obtainable by" claims, they are no panacea and present their own conceptual difficulties. The point of such a claim is to cover a product which was not made by the defined process but could have been. One might ask how a product which was in fact made one way could ever have been made a different way. What the process language in these kinds of claims is really intended to be referring to is a particular characteristic or characteristics of the product. So in the ***Johnson Matthey*** case cited in argument (T956/04) the patentee wanted to define the product (a catalyst) by reference to the size distribution of crystallites. The information in the patent would allow them to specify actual values for other characteristics (such as preferred amounts of cobalt) but the only way to define the product by reference to the characteristic of crystallite size distribution was by reference to the process conditions which produced that particular distribution.
>
> **132.** In other words what the patentee was trying to do was claim a product irrespective of how it was made but with a particular characteristic which is the same characteristic which results from using a given process. If it is clear what the characteristic is and is true that in fact process conditions can be specified which do produce the given characteristic then one can see why this makes sense. Claim 1 in ***Johnson Matthey*** used the "obtainable by" language."

44. Reverting then to how the usage of those expressions may have a bearing on the construction of product-by-process claims, the Court observed:-

> "**134.** The view taken by the EPO in the 1980s (see e.g. ***IFF / Claim Categories*** T150/82 and later cases T248/85 and T219/83) was firmly against the idea that an old thing could be patented using product by process language. The EPO held that

defining a product by the process by which it was made could not confer novelty on a product which was known *per se*. The product itself had to be novel. In effect in these cases the EPO was deciding to treat "obtained by" claims and "obtainable by" claims in the same way, at least for its purposes, i.e. for validity. Regardless of the claim wording, all claims were treated as if they meant "obtainable by". If the process conferred a particular characteristic on the product then one could take that characteristic into account. But if not, then the process feature made no difference and the product was not different from the prior art. The product would lack novelty.

135. The EPO's approach to overt product by process claims today is settled. They will be permitted (and only permitted) if there is no other way of defining the product open to the patentee. This is a decision based on policy. Such claims present clarity problems and are best avoided but if there is no alternative way of defining the characteristic in question, then they will be permitted.

136. But despite their apparently esoteric nature (even by the standards of patents) product by process language is actually quite common and hardly remarked upon. Claim 1 of 628 as granted is a product claim which uses process language in an unexceptional way. The opening words are "*A formulation comprising a lyophilised mixture of…*". This is a claim to a product defined by reference to the process by which it has been made. Claims drafted this way are granted routinely and rarely raise any issue. No-one calls these claims product by process claims and the EPO does not apply its case law to this language. That is why I referred to "overt" product by process claims in the previous paragraph.

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139. In ***Kirin-Amgen*** the Court of Appeal had held that the product by process claim (claim 26) was novel because of the novel process feature. The Court of Appeal had refused to follow the EPO's practice about permitting such claims only in certain circumstances because that was a rule of practice of no concern to national courts. Lord Hoffmann (with whom the other lords agreed) did not agree with the Court of Appeal's reasoning (paragraphs 98-101). He held that a difference in the method of manufacturing did not make a product new and that was so as a matter of law. On that basis the claim could only be novel if the process definition gave the product a new characteristic of some kind. On the finding of fact in ***Kirin-Amgen***, therefore claim 26 lacked novelty since the process did not necessarily do so. The decision of the Court of Appeal was wrong. The UK should follow the approach of the EPO.

> **140.** Therefore the ratio of the decision in ***Kirin-Amgen*** is that an identical product made by a new process does not count as new. In that respect the UK now follows the EPO. Lord Hoffmann did not agree with the Court of Appeal's decision but the focus of his disagreement was not about the EPO's rule of practice, the issue was that there was a point of law underpinning that practice. Lord Hoffmann was concerned to align the UK law of novelty with the law applied in the EPO. Beyond a need for a claim to be novel, he was not commenting on whether the EPO's practice was sound or not and did not comment on the Court of Appeal's refusal to follow it as a rule of practice only, subject to applying the correct law of novelty."

45. The Court ultimately culled out the following principles which would govern:-

> "**147.** I derive the following principles from this consideration of the EPO and UK authorities:
>
> i) A new process which produces a product identical to an old product cannot confer novelty on that product. To be novel a product obtained or obtainable by a process has to have some novel attribute conferred on it by the process as compared to the known product.
>
> ii) This rule is a rule of the law of novelty. It is not a principle of claim construction. Although in effect the rule treats "obtained by" language as "obtainable by" language, nevertheless as a matter of claim construction a claim to a product "obtained by" a process means what it says. That will be the relevant scope of the claim as far as infringement and sufficiency are concerned.
>
> iii) Although normally a patent is drafted by the inventor "in words of his own choosing", the EPO will not permit overt product by process language unless there is no other alternative available. By no other alternative, they mean no other way of defining a particular characteristic of the product in question."

46. *Hospira UK Limited* apart from the above also carries the following significant conclusions:-

> "**156.** I turn to consider and try to apply the EPO's practice of permitting overt product by process claims only if there is no alternative. Genentech contends it is clear that the EPO's approach is satisfied because there is no alternative to the product by process claim. No other potentially valid claim

presents itself (save for proposed claim 2, which I can ignore for now at least on the basis that it will only matter if in the end claims 1 and 2 are both otherwise valid, in which case I may need to return to this). The granted claims can be assumed to be invalid and no other option has been identified.

157. I confess that trying to apply the EPO's stated approach is not easy but my tentative conclusion is that Genentech's submission is wrong. The EPO's practice is not that product by process claims are a sort of last resort when all else fails in the sense that every other claim is invalid. That sort of approach would be unprincipled. On that basis they would be available in all cases. Since the EPO's practice runs counter to the idea that a patentee is entitled to use words of his own choosing in describing his invention, it must be based on some principle. The principle underlying the EPO's practice is shown by the ***Johnson Matthey*** case. It is a principle of clarity (Art 84 EPC, s14 of the 1977 Act) and amounts to a trade off between clarity and fairness, tolerating an increased lack of clarity in that limited class of cases. If a patentee can identify a characteristic or parameter disclosed in the patent for which no other definition is available in the specification other than an "obtainable by" process definition, then a product by process claim may be allowed as a way of claiming that attribute. It is impossible to apply that approach properly without knowing what characteristic the process feature is to be used to define. That would be best stated in the claim expressly but it may be clear from the specification.

158. Proposed claim 1 of 628 does not expressly state which characteristic is referred to. The skilled reader could draw up a list of characteristics but they would not know which one was intended either from the claim or from the specification as a whole. The only realistic conclusion is that every conceivable characteristic is caught by the definition. Maybe in some cases that would not cause a difficulty but here to say that every feature is relevant leaves the reader with the impossible task of having to create for themselves a list of relevant attributes. The fact the skilled reader would include molar ratio on the list does not help.

159. Not without some hesitation, it seems to me that a principled application of the EPO's stated approach must lead to refusal of this amendment. My hesitation derives from the fact that I suspect in practice the EPO has permitted product by process claims in the past even when they do not expressly recite the attribute(s) to which the language applies. However since the reader of claim 1 of 628 cannot identify all the attributes to which the language applies, I do not see how I can permit a claim in that form. The fact the skilled reader of the

> 628 patent can identify one attribute is not sufficient since the reader would understand that there would in all likelihood be further attributes to which the product by process language also applies but that would be an indefinite class of attributes. Accordingly I will not permit the amendments to allow proposed claim 1 of 628 nor proposed claims 1 and 3 of 119. It makes no difference whether these claims use the words "consisting of" rather than "comprising".

47. It was in the aforesaid light that Mr. Kaul and Mr. Anand submitted that *Hospira UK Limited* had clearly recognized the protection which a product could claim even though it may have been described by way of a process of manufacture. Learned counsels assailed the impugned judgment contending that the learned Single Judge failed to even extract or consider the most crucial paragraph in *Hospira UK Limited*, namely, para 147 and which embodied the principles which were articulated. It was their submission that it was never the case of the appellants that an old product could be patented even though it may lack novelty or inventiveness. It was their submission that the learned Single Judge also failed to appreciate that the claim of the suit patent uses the phrase “obtainable from” and which according to *Hospira UK Limited* must be interpreted to mean the claim covering the product per se and the process being merely illustrative.

48. The position as prevailing in the EU was sought to be explained firstly with reference to the guidelines framed by the EPO and which have been extracted hereinabove. Learned counsels laid emphasis on the fact that the EPO follows the principle of the terms ‘obtainable’, ‘obtained’, ‘directly obtained’ or any other words of equivalent characteristic as being inconsequential since product-by-process claim are principally directed towards the product and confer absolute protection upon the same. Significantly the EPO guidelines also

stipulate that the burden of proof for distinguishing a product-by-process feature lies upon the applicant who must by way of evidence establish that the modification of the process parameters results in the invention or creation of another product. This according to learned counsels would also be in tune with Section 48 of our statute and which enables a patentee to injunct a person from using a process which is patented and which when replicated results in the production of a product which is found to have been obtained directly by that process. Not only this, according to learned counsels, since a product-by-process would constitute an amalgam of the protections accorded by both clauses (a) and (b), similar would be the uncontestable conclusion which one would arrive at if one were to test them on the anvil of novelty. The submission essentially was that the adoption of a process which may be different from the one which forms part of a product-by-process claim would not cross the threshold of non-infringement unless it is established that the process has led to the creation of a novel or new product.

49. Insofar as the position in the EU is concerned, the appellants also drew our attention to the passages from the decisions in *International Flavors*, which has been extracted hereinabove. The appellants then took us to the holding of the *en banc* Court in *Abbott Laboratories* and which affirmed the position voiced in *Atlantic Thermoplastics* and departed from the views which were expressed in *Scripss*. The appellants drew our attention to the following passages as appearing in the minority opinion:-

> "Defying precedent, the en banc court adopts for all situations "the basic rule that the process terms limit product-by-process claims," maj. op. at 17, whether the product is novel or known, and whether or not the new product could not have been fully

described by its structure alone. The court eliminates the long-accepted expedient for new products whose structure is not fully known. While the Scripps decision is the only decision that is mentioned as "expressly overruled," maj. op. at 17, Scripps is only one of many cases now discarded.

The en banc majority's response to the dissenters is to state that "the inventor is absolutely free to use process steps to define this product" if its "structure is either not fully known or too complex to analyze," maj. op. at 19, but to eliminate the premise that the inventor thereby obtains a product claim, not a process claim. According to the majority, a patentee can continue to obtain product claims using process descriptors, but such product claims are treated as process claims for infringement. The applicant would still have to demonstrate patentability of the new product as a product (independent of the process), while enforcement of the patent against an identical product would be limited to the infringer's use of the process steps used as a descriptor. For the first time, claims are construed differently for validity and for infringement.

It has been an inviolate rule that patent claims are construed the same way for validity and for infringement. See, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc., 324 F.3d 1313, 1330 (Fed. Cir. 2003) ("It is axiomatic that claims are construed the same way for both invalidity and infringement."); Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1363 (Fed. Cir. 1998) ("Claims must be interpreted the same way for determining infringement as was done to sustain their validity."); Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."); Beachcombers, International, Inc. v. WildeWood Creative Products, Inc., 31 F.3d 1154, 1163 (Fed. Cir. 1994) ("We have already interpreted the claims for purposes of assessing their validity. The same claim interpretation of course applies to the infringement analysis."); Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("claims must be construed the same way for validity and for infringement"); Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 882 (Fed. Cir. 1988) ("The claims of the '970 patent measure the invention at issue; thus, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); see also 5A Chisum on Patents §18.01 (2007) ("A fundamental tenet

of patent law is that a claim must be interpreted consistently for purposes of infringement and validity."); id. §18.03[2][h] (collecting cases).

As interpreted for validity, the claims obtained under the expedient of necessity are product claims, and are subject to the requirements of novelty, unobviousness, and all other requirements for new products, independent of how the products can be made. My colleagues hold that these are product claims for validity, but process claims for infringement. Departure from the rule that forbids such deviation requires sound reason, and fuller exploration than the cursory brush-off dispensed by my colleagues.

I do agree with my colleagues that their logic is "simple." Maj. op. at 19. However, today's inventions are not simple. The needs of inventions of the past and present, and more so the future, are not simple. The public interest in invention and development of today's complex sciences, is not simple. The en banc court's "simple" hypothetical about "compound X, obtained by process Y," is simply irrelevant to the issues we must resolve. Scientists know that it is often easier to show that two products are the same, than to decipher their chemical or biological structure; for example, in the case at bar, comparing the X-ray diffraction patterns and absorption spectra could show that the products are the same, although their exact crystal structure is undefined. However, my colleagues announce that the only way to establish whether the accused compound is the same as the patented compound is by inquiring whether they were prepared by the same method. Maj. op. at 19-20 ("[W]hat analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes?"). That question has many answers, now stated to be irrelevant.

While the section of this opinion decided by the en banc court is largely directed to its reversal of precedent, the implementation of its ruling remains with the original panel. The panel decision enlarges the en banc ruling, further binding this court. The claims at issue state processes by which the new crystal form is "obtainable," although the specification states that other methods might be used. The panel rules that a claim "cannot capture a product obtained by or obtainable by processes other than those explicitly recited in the claims." maj. op. at 21, finding authority in BASF, which I have discussed ante. My colleagues thus continue to misapply the Court's ruling in BASF, where the Court stated repeatedly that the product in that case was a known product. BASF, 111 U.S. at 311 ("It was an old article."). In BASF the Court responded to the patentee's argument that it was entitled to cover all artificial alizarine made

by any process, by observing that the patentee had not shown how the infringing and patented products "can be recognized," id. at 310, an aspect at the opposite pole from the case at bar, where the patentee provided elaborate details as to how the patented and accused crystal forms can be recognized.

The panel also states that "the applicant's statement in the file wrapper that 'the method of preparation . . . is not considered the heart of the present invention' should not be afforded undue gravitas." Maj. op. at 22. This too is an aberration of precedent, and is contrary to the many rulings of the Supreme Court and this court that afford due gravitas to the applicant's statement of what has been invented. See, e.g., BASF, 111 U.S. at 308 ("It is very plain that the specification of the original patent, No. 95,465, states the invention to be a process for preparing alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine, to be prepared, however, by the new process, which process is to be the subject of the patent . . . ."); Plummer v. Sargent, 120 U.S. at 443 (quoting specification of companion patent, where inventor stated "My invention consists in a process of covering iron with a very thin coating of oil, and then subjecting it to heat, the effect of which is to leave upon the iron a firm film, which is very durable, and gives the iron a highly ornamental appearance, like that of bronze"). The Federal Circuit's emphasis on the importance of the specification has been repeatedly stated. E.g., Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) ("[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." (internal quotation marks omitted)).

The en banc court appears to misjudge the implications of its ruling, for the court states that it is now making available to "others the right to freely practice process Z [a different process] that may produce a better product in a better way." Maj. op. at 20. If others can indeed make a better product, this expedient presents no impediment. That is not the issue of this case. The issue is the right to make the same product, by making a process change that does not change the product. By now assuring that right, the exclusionary value of the claim to a new product is lost.

The purpose of the rule of necessity is to allow inventors of complex new products to obtain the patent scope to which their invention is entitled—the scope of the novel product they invented, no more and no less. The majority's change of law simply emposes unfairness as well as legal error on patent-supported advances."

50. According to Mr. Kaul, contrary to the consistent body of precedent which had evolved in the United States and which had held that claims must be construed in the same manner, be it for validity or for infringement, the majority in *Abbott Laboratories* constitutes a stark departure from that principle and thus inviting severe criticism. It was submitted that insofar as the provisions contained in our statute is concerned, they neither make such a distinction, nor would the adoption of the *Abbott Laboratories* principle be valid under the scheme of the Act.

51. According to Mr. Anand, the IPO Guidelines themselves are a resounding answer to this contention of the respondents. It was contended that the cardinal principle of a patent claim being construed in an identical manner both while considering validity as well as infringement is one which was recognized as far back as in **European Central Bank vs. Document Security Systems Inc.**[17] and where this position was enunciated and has since then come to be popularly known as the "Angora Cat" principle. Reference was made to the following passages from that decision: -

> "**5.** All this is deeply regrettable. It illustrates yet again the need for a one-stop patent shop (with a ground floor department for first instance and a first floor department for second instance) for those who have Europe-wide businesses. The case illustrates another point too: Kitchin J records at [88] that "the positions adopted by DSS before this Court and the CFI are radically different." As he went on to say:
>
> > This case therefore seems to me to be a very powerful illustration of why it is desirable to try infringement and validity issues together, where at all possible. If they are tried separately it is all too easy for the patentee to argue for a narrow interpretation of his claim when defending it

[17] [2008] All ER (D) 277 (Mar)

> but an expansive interpretation when asserting infringement.
>
> Professor Mario Franzosi likens a patentee to an Angora cat. When validity is challenged, the patentee says his patent is very small: the cat with its fur smoothed down, cuddly and sleepy. But when the patentee goes on the attack, the fur bristles, the cat is twice the size with teeth bared and eyes ablaze."

52. It was submitted in light of the above that since the rights of a patentee are secured and defined by the claims, they cannot possibly be interpreted broadly at the time of securing such a right and in a limited or constricted fashion at the time of enforcement. It was submitted that the acceptance of the contentions addressed by the respondents and which has found favor with the learned Single Judge would disincentivise patentees from seeking the grant of a patent for a new and inventive product since it would become impossible for the patentee to enforce the same. It was thus contended that the line as struck by the majority in *Abbott Laboratories* must be disavowed.

53. The appellants also sought to draw sustenance from the judgment handed down by the Supreme Court of Japan in **2012 (Ju) 1204**[18] where while dealing with product-by-process claims, the following significant observations came to be made:-

> "(1) The recitation of a claim attached to a patent application plays a role of the basis for determining the technical scope of a patented invention (Article 70, paragraph (1) of the Patent Act), and also for identifying the gist of the invention claimed in a patent application, which serves as the premise for examining the requirements of patentability prescribed in Article 29 of said Act (see 1987 (Gyo-Tsu) No. 3, judgment of the Second Petty Bench of the Supreme Court of March 8, 1991, Minshu Vol. 45, No. 3, at 123). A patent is to be granted for an invention of a product, an invention of a process or an invention of a process of producing a product. If a patent has been granted for an invention of a product, a patent right relating to that patent is

[18] Minshu Vol. 69,No.4

effective against any products that have the same structure, characteristics, etc. as those of the product subject to the invention, irrespective of the manufacturing processes of these products.

Consequently, it is appropriate to construe that even when a claim of a patent for an invention of a product recites the manufacturing process of the product, the technical scope of the patented invention should be determined as being limited to products that have the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim."

54. The appellants also questioned the contention addressed by the respondents and who sought to draw support from the divisional applications which the appellants came to file before the **United States Patent and Trademark Office**[19] and the EPO. The aforenoted submission was addressed in the backdrop of a comparative table which was presented by the respondents and who had argued that nothing restrained the appellants from moving a divisional application if they sought protection of FCM as a product. For ease of reference that Table is extracted hereinbelow: -

Parent Patents			**Divisional Patents**		
IN 221536	**EP 1554315**	**US7612109**	**EP2278204**	**US20140371169**	**US20160215071**
Water soluble iron carbohydrate complexes obtainable from an aqueous solution of iron III salt and an aqueous solution of the oxidation product of one	Water soluble iron carbohydrate complex having a weight average molecular weight (Mw) of 80 kDa to 400 kDa obtainable from an	A water soluble iron carbohydrate complex having a weight average molecular weight (Mw) of 80,000 to 400,000, comprising the reaction	Water soluble iron(III)-carbohydrate complexes on the basis of the oxidation products of maltodexti	An iron Carboxypolymaltose complex of formula: [Fe0x(OH)y(H20)zin[{c6H1005).(c6H1207) } ilk wherein the values for	An iron Carboxypolymaltose complex of formula: [FeOx(OH)y(H2O)x]n[{C6H10O5)(C6H12O 7)}]Ik

[19] USPTO

or more maltrodextrins using an aqueous hypochlorite solution at a pH-value within the alkaline range where when one maltodextrin is applied its dextrose equivalent lies between 5 and 20 and when a mixture of several maltodextrins is applied the mixture lies between 5 and 20 and the dextrose equivalent of each individual maltodextrin contained in the mixture lies between 2 and 40 wherein the obtained iron complexes have an average molecular weight of 80 kDa to 400 kDa.	aqueous solution of iron (III) salts and an aqueous solution of the oxidation product of one or more maltodextrins using an aqueous hypochlorite solution at a pH-value within the alkaline range, where, when one maltodextrin is applied, its dextrose equivalent lies between 5 and 20, and when a mixture of several maltodextrins is applied, the dextrose equivalent of the mixture lies between 5 and 20 and the dextrose equivalent of each individual maltodextrin contained in the mixture lies between 2 and 40.	product of: (a) an aqueous solution of an iron (III) salt and (b) an aqueous solution of the oxidation product of (i) at least one maltodextrin and (ii) an aqueous hypochlorite solution at an alkaline pH, wherein, when one maltodextrin is present, the maltodextrin has a dextrose equivalent of between 5 and 20, and wherein, When a mixture of more than one maltodextrin is present, the dextrose equivalent of each individual maltodextrin is between 2 and 40, and	ns, wherein the iron (III) carbohydrate complexes have a weight average molecular weight Mw of 80 KDa to 400 kDa.	variables x, y, z, n, m, 1 and k are such that said iron carboxypolymaltose complex has an average molecular weight in the range of from about 80 kDa to about 400 kDa and an iron content in the range of from about 24 to about 32% by weight.	Wherein the values for variables x, y, z, n, m, 1 and k are such that said iron Carboxypolymaltose complex has an average molecular weight in the range of from 80 kDa to about 400 kDa and an iron content in the range of from about 24 to about 32% by weight.

		the dextrose equivalent of the mixture is between 5 and 20.			

55. Explaining the circumstances which had constrained the appellants to file divisional applications before the EPO and the USPTO, it was submitted that the following events would shed light on the route which the appellant pursued. The aforesaid contention proceeded in light of the following Table: -

EVENT	DATE
Date of grant of the Suit Patent, *i.e., cut-off date for filing a divisional application in India, assuming other conditions therefor have been fulfilled.*	25th June 2008
Date of the US decision in *Abbot v. Sandoz*, which changed US law pertaining to Product by Process claims	18th May 2009
Date of grant of US 7612109	3rd November 2009
Date of grant EP 1554315	27th April 2011
Date of application for the divisional patent application EP 2278204	23rd February 2011
Date of application for the downstream divisional/continuation patent application US 20140371169	27th August 2014
Date of application for the downstream divisional/continuation patent application US 20160215071	1st April 2016

56. It was submitted that the aforesaid facts would unequivocally establish that the appellant was constrained to file divisional applications consequent to the change in the law which was ushered in by *Abbott Laboratories*. According to the appellants, it was this abrupt change in the US position which had prompted the appellants to file divisional applications out of abundant caution. In any case, Mr. Kaul and Mr. Anand submitted, the filing of the divisional applications cannot be viewed as negatively impacting the stand of Vifor, since the

opposition Division in the EPO has clearly held that the subject matter of the divisional does not exceed the scope of the independent product-by-process claims forming part of the parent EU patent.

57. Mr. Kaul and Mr. Anand then submitted that the learned Single Judge has committed a manifest illegality in failing to bear in mind the injunctions and favorable orders which had been granted to the appellant in nearly 20 lawsuits. According to learned counsels, those orders which stand compendiously placed on the record would itself have sufficed for the purposes of grant of interim injunction.

58. The impugned judgment was also assailed on the ground of the learned Single Judge having manifestly erred in understanding the stand of the appellant which had right from the stage of presentation of the plaint asserted Claim 1 as constituting a product claim and additionally describing the same to be a product-by-process claim. It was contended that the appellants had throughout asserted that the claim of the suit patent had been worded in a product-by-process format. This stand of the appellants according to learned counsels is clearly reflected in paragraphs 9, 12, 17 and 18 of the impugned judgment itself. According to the appellant, the learned Judge has erroneously taken the view that the appellant had asserted its claims as being one relating to a process alone. It was vehemently argued that the learned Single Judge has incorrectly appreciated the submissions addressed by the appellant as denying the existence of product-by-process claims under Indian Patent law. It is submitted that the appellant had categorically asserted that the claim despite being in a product-by-process format clearly sought extension of protection to the product itself. It was in the aforesaid backdrop that learned counsel submitted that the learned

Judge erroneously observes in paragraph 54 of the impugned judgment that the stand of the appellant was that the statutory regime in India does not recognize product-by-process patents. It was in this regard further submitted that it was the appellants who had cited the IPO guidelines and the learned Judge could not have possibly or justifiably appreciated the contentions advanced as being that product-by-process claims are unknown under the Indian Patent regime. It was submitted that the appellants had on more than one occasion sought to emphasize the imperatives of structuring claims in a product-by-process format bearing in mind the complexities of FCM and their inability to describe the same in a conventional sense and in the form of a formula or chemical structure. It was the submission of learned counsels that the only way to describe FCM was to refer to an exemplary process for the preparation of the product. According to Mr. Kaul and Mr. Anand, despite the aforesaid submissions being reflected in paragraphs 17 and 20, the learned Judge has held to the contrary and against the appellants.

59. The impugned judgment was also assailed on a clear failure on the part of the learned Single Judge to take into consideration the order of the EPO dated 14 September 2016 which was a document of criticality and fairly laid to rest all controversies that were raised.

60. The impugned judgment was also assailed on the ground of the learned Single Judge having selectively quoted from expert opinion which was tendered by Sir Robin Jacob, a former Lord Justice of the UK Court of Appeals and eminent jurist, and failing to consider the crucial averments in the affidavit of the expert who had in unequivocal

terms averred that from a UK perspective, FCM would have been considered as relating to a product.

61. It was lastly urged that even the balance of convenience lay in favor of the appellants bearing in mind the undisputed fact that it held equivalent patents across 57 jurisdictions and had enjoyed protection for over 20 years. It was submitted that neither the suit patent nor its foreign counterparts had ever been successfully challenged. It was the submission of Mr. Kaul and Mr. Anand that the novelty of FCM as a product has been clearly overlooked by the learned Single Judge and this itself warranting the impugned order being set aside.

D. SUBMISSIONS OF MSN & DR. REDDY'S

62. Appearing for MSN Laboratories and Dr. Reddy's Laboratories, Mr. Nataraj at the outset commended for our consideration the well settled principle relating to the powers of an appellate court to interfere with a discretionary order. Learned counsel laid emphasis on the well settled principles in this regard as propounded in **Wander Ltd. and Anr. vs. Antox India P. Ltd**[20]. It was his submission that the learned Judge had followed and applied the well settled principles governing the grant or refusal of interlocutory injunction and since the impugned decision did not suffer from any patent or manifest errors, the appeals were liable to be dismissed on this score alone.

63. It was the submission of Mr. Nataraj that the impugned judgment follows the well-established jurisprudence relating to the interpretation of product-by-process claims and which the learned Judge has rightly noted would entail novelty vesting in the specified process features of a claim. According to Mr. Natraj, the appellants cannot be permitted to

[20] 1990 (Supp) SCC 727

assert that Claim 1 of IN'536 is a product claim since it was their consistent stand as reflected in the plaint also that Claim 1 was a product-by-process claim.

64. Mr. Nataraj submitted that it is open to a defendant in a patent infringement suit to raise the defenses of invalidity as well as non-infringement. According to learned counsel, the respondents have assailed the validity of the suit patent in the written statements filed and therefore it would be incorrect for the appellant to contend that the validity of IN'536 had not been questioned. According to Mr. Nataraj, the respondents have merely desisted from pressing the ground of invalidity at the stage of consideration of the interim injunction application.

65. Proceeding then to the issue of claim construction, it was submitted that the basic tenet of patent law around the world, and which is followed even in India, relates to the precept of patent bargain and which entails the conferral of a limited monopoly upon the patentee in exchange for the disclosure of the invention for which the monopoly is sought and which work or invention can be beneficially used by the public on the expiry of the patent term. According to learned counsel, the principal function of the claim is to define the scope of the invention and which also stands mirrored in Section 10(4)(c) of the Act. It was submitted that the aforesaid provision defines the scope of the monopoly by stipulating that the claims define the scope of the invention. Reliance in this respect was placed on the decisions rendered in **FMC Corporation and Ors. vs Natco Pharma Limited**[21] which was upheld by the Division Bench in **FMC Corporation and Ors. vs**

[21] 2022 SCC OnLine Del 2994

Natco Pharma Limited [22] and followed in **FMC Corporation and Ors vs. Insecticides India Limited**[23]**.** According to Mr. Nataraj, the propositions and principles enunciated in the aforenoted judgments are in tune with international patent jurisprudence.

66. Insofar as claim construction of product-by-process claims are concerned, Mr. Nataraj sought to draw sustenance from the principles laid down in *Atlantic Thermoplastics* and *Abbott Laboratories*. It was the submission of Mr. Nataraj that the process terms forming part of a product-by-process claim limit the scope of protection claimed and insofar as infringement actions are concerned, courts would confine their scrutiny to the process alone. According to Mr. Nataraj, tested on the anvil of Section 48 of the Act, it would be evident that Claim 1 of IN'536 stands confined to a process alone. It was submitted that Claim 1 seeks protection for FCM manufactured by a specified method in order to define the purported invention. According to learned counsel, since claims define the scope of protection, every element thereof is relevant. Mr. Natraj submitted that even if the end result of the claim be a product, the monopoly is not defined by the product per se but by the language in which the claim is couched. Our attention was drawn to Section 2(1)(m) of the Act and which defines inventions as a new product or process involving an inventive step and capable of industrial application. In view thereof, it was contended that the Act recognizes only two categories of inventions, namely, a product or a process. Mr. Nataraj pointed out that a reading of Claim 1 shorn of process limitations would establish that the same relates to a "water soluble iron carbohydrate complexes having average molecular weight of 80 kDa to

[22] 2022 SCC OnLine Del 4249
[23] 2022 SCC OnLine Del 3769

400 kDa". According to learned counsel, as per the written description of IN'536, water soluble carbohydrate complexes were already known in the prior art. More importantly, according to Mr. Nataraj, the complete specification stood dedicated to describing process features and not the product itself.

67. Mr. Nataraj also sought to highlight what according to him, were admissions made by the appellants in the suit proceedings when asserting in the plaint itself that claim 1 was a product-by-process claim. It was submitted that even in the responses filed before the IPO, the appellant had asserted that the essence of the invention lies in oxidizing the selected maltodextrin to obtain an oxidized maltodextrin complex. It was argued that while responding to Documents D1 and D2, which was cited by the IPO, the appellants had contended that the complexes obtained by the process of Claim 1 are novel and the process itself is also novel, since different starting materials are used. According to learned counsel, all of the above would clearly point towards Claim 1 being merely a product-by-process claim.

68. Mr. Nataraj also questioned the assertion of the appellants when they had contended that Claim 1 was structured as such since at the relevant time the appellants were unable to adequately describe the invention except in process terms. According to Mr. Nataraj, the aforesaid submission is liable to be outrightly rejected since FCM in terms of a chemical formula and structure was known as far back as in 2006 and thus nothing stopped the appellants from moving a divisional application under the Act. The conduct of the appellant, according to Mr. Nataraj, must also be weighed bearing in mind the divisional applications which it chose to present before the USPTO and the EPO

while choosing not to follow that route in India. It was in the aforesaid backdrop that Mr. Nataraj submitted that since the appellant voluntarily chose not to file a divisional application and to amend IN'536 to include a claim limited to a structure or a formula despite Sections 57 to 59 of the Act permitting incorporation of an actual fact, it cannot now seek to reclaim this in infringement proceedings.

69. Mr. Nataraj then placed reliance on the following principles which came to be enunciated by the majority in *Abbott Laboratories*: -

> "Thus, based on Supreme Court precedent and the treatment of product-by-process claims throughout the years by the PTO and other binding court decisions, this court now restates that "process terms in product-by-process claims serve as limitations in determining infringement." Atl. Thermoplastics, 970 F.2d at 846-47. As noted earlier, this holding follows this court's clear statement in In re Thorpe that "product by process claims are limited by and defined by the process." 777 F.2d at 697.
>
> More recently, the Supreme Court has reiterated the broad principle that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." Warner-Jenkinson, 520 U.S. at 19. Although Warner-Jenkinson specifically addressed the doctrine of equivalents, this rule applies to claim construction overall. As applied to product-by-process claims, Warner-Jenkinson thus reinforces the basic rule that the process terms limit product-by-process claims. To the extent that Scripps Clinic is inconsistent with this rule, this court hereby expressly overrules Scripps Clinic.
>
> xxxx xxxx xxxx
>
> Product-by-process claims, especially for those rare situations when products were difficult or impossible to describe, historically presented a concern that the Patent Office might deny all product protection to such claims. See In re Butler, 17 C.C.P.A. 810, 813 (CCPA 1930) ("Process claims are valuable, and appellant thinks he is entitled to them; but it is submitted that he should not be limited to control of the process when the article which that process produces is new and useful."). In the modern context, however, if an inventor invents a product whose structure is either not fully known or too complex to analyze (the subject of this case – a product defined by sophisticated PXRD technology – suggests that these concerns

may no longer in reality exist), this court clarifies that the inventor is absolutely free to use process steps to define this product. The patent will issue subject to the ordinary requirements of patentability. The inventor will not be denied protection. Because the inventor chose to claim the product in terms of its process, however, that definition also governs the enforcement of the bounds of the patent right. This court cannot simply ignore as verbiage the only definition supplied by the inventor.

This court's rule regarding the proper treatment of product-by-process claims in infringement litigation carries its own simple logic. Assume a hypothetical chemical compound defined by process terms. The inventor declines to state any structures or characteristics of this compound. The inventor of this compound obtains a product-by- process claim: "Compound X, obtained by process Y." Enforcing this claim without reference to its defining terms would mean that an alleged infringer who produces compound X by process Z is still liable for infringement. But how would the courts ascertain that the alleged infringer's compound is really the same as the patented compound? After all, the patent holder has just informed the public and claimed the new product solely in terms of a single process. Furthermore, what analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes? If the basis of infringement is not the similarity of process, it can only be similarity of structure or characteristics, which the inventor has not disclosed. Why also would the courts deny others the right to freely practice process Z that may produce a better product in a better way?

In sum, it is both unnecessary and logically unsound to create a rule that the process limitations of a product-by-process claim should not be enforced in some exceptional instance when the structure of the claimed product is unknown and the product can be defined only by reference to a process by which it can be made. Such a rule would expand the protection of the patent beyond the subject matter that them inventor has "particularly point[ed] out and distinctly claim[ed]" as his invention, 35 U.S.C. § 112 ¶ 6.

xxxx xxxx xxxx

In sum, a patentee's use of the word "obtainable" rather than "obtained by" cannot give it a free pass to escape the ambit of the product-by-process claiming doctrine. Claims that include such ambiguous language should be viewed extremely narrowly. If this court does not require, as a precondition for infringement, that an accused infringer actually use a recited process, simply

> because of the patentee's choice of the probabilistic suffix "able," the very recitation of that process becomes redundant. This would widen the scope of the patentee's claims beyond that which is actually invented—a windfall to the inventor at the expense of future innovation and proper notice to the public of the scope of the claimed invention. For all the above reasons, the Eastern District of Virginia correctly construed the process limitations beginning with "obtainable by" in claims 2-5 as limiting the asserted claims to products made by those process steps"

70. It was his contention that *Abbott Laboratories* rightly finds and holds that once the inventor chooses to claim the product in terms of its process that definition should govern enforcement and the bounds of the patent right. According to Mr. Nataraj, *Abbott Laboratories* rightly holds that it would be illogical to create a rule of uncertain application that process limitations of a product-by-process claim should not be enforced in some exceptional instances where the structure of the claimed product be unknown or where the product cannot be defined but with reference to a process. Emphasis was laid on *Abbott Laboratories* ultimately holding that the adoption of such a rule would expand the protection of the patent beyond the subject matter that the inventor had distinctly claimed. Mr. Nataraj further submitted that the arguments addressed upon the meaning to be ascribed to the phrase "obtainable by" cannot confer a right on a patentee to use ambiguous terms in a claim and thereby render those terms redundant. It was submitted further that a comparative reading of the filings before the USPTO and the EPO would establish that claims with respect to FCM had been recited without the aid of process elements.

71. Mr. Nataraj also emphasized on the **World Health Organization**[24] and **United States Adopted Name**[25] Council having

[24] WHO
[25] USAN

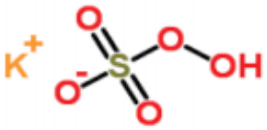
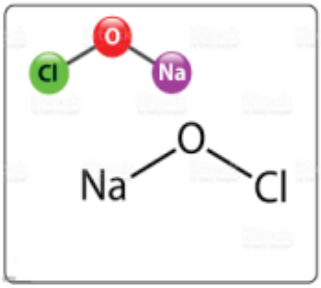
allocated a chemical name of FCM in 2006 and 2008 itself. In view of the aforesaid, he submitted that it would be wholly incorrect for the appellant to contend that IN'536 was incapable of being defined in ordinary terms. Insofar as the allegation of infringement is concerned, it was the submission of Mr. Nataraj that the appellants essentially seek the Court to undertake a comparative analysis of the product of the appellant and the respondents and which is clearly impermissible. According to learned counsel, the issue of infringement must be answered on a comparison of the claims of the infringing products. It was submitted that this Court itself had disapproved the "product to product" comparison in *F.Hoffmann-La Roche*. It was submitted that as would be evident from the following passages of *F.Hoffmann-La Roche*, it is evident that infringement analysis is to be carried out on an interpretation of the claims and then comparing the claims so construed with the allegedly infringing product:-

> "**107.** Thus, it is apparent that the Learned Single Judge has referred to two distinct things i.e. Claim 1 of IN '774 and Tarceva, interchangeably, to determine the infringement question and comes to what appears to us to be an erroneous conclusion.
>
> **108.** At this stage it is important for us to make some observations on X-ray diffraction as a methodology to ascertain infringement. X-ray diffraction is a method to determine and understand the crystalline structure of a compound. It is primarily used for the following broad purposes:
>
> • In the regulatory field or during drug development, to identify a compound.
>
> • To distinguish between amorphous and crystalline compounds.
>
> • To identify the fingerprints of various polymorphic forms of a compound.
>
> **109.** X-ray diffraction is certainly not an accurate method to ascertain product patent infringement in the present case as the issue is not and indeed cannot be whether Roche and Cipla's products are identical but whether Cipla's product is covered in

> the claims of Roche's patent. Although this appears to us to be a fairly elementary issue in appreciation of the nature of evidence in product patent infringement cases, neither counsel have relied on any jurisprudence to demonstrate what ought to be the correct test of infringement of a product patent.
>
> **110.** While this issue was indeed framed by the Division Bench of the Gujarat High Court in the decision reported as 2008 (37) PTC 128 (Guj) Hind Mosaic and Cement Works v. Shree Shahjanand Trading Corporation in the following words: *"an infringement analysis involves comparison of each and every limitation of the claim with the allegedly infringing device. The analysis cannot be performed by comparing the product manufactured by the patentee with the allegedly infringing product*," the decision does not expressly address this question. Since no other judgement has been brought to our attention which sets this issue right, we feel it is important for us to underscore it here.
>
> **111.** It is an incorrect analysis of product patent infringement in a case like the present, to use methodologies like X-Ray diffraction to ascertain whether the competing products are identical in nature. The correct test of infringement in this case is to map Cipla product against the Roche's patent claims, which we find has not been done by the learned Single Judge, and this is the third infirmity on this aspect of the dispute."

72. It was his submission that what is infringed is a claim of a patent and not a product. In view of the aforesaid, it was his submission that the repeated assertion of the appellants that FCM was novel is clearly of no relevance. Mr. Nataraj submitted that once Claim 1 of the suit patent is acknowledged to be a product-by-process claim, the Court must hold that it would stand circumscribed by the process elements and therefore the question of infringement being answered only if it be established that the respondents had employed an identical process.

73. It was in this connection submitted that as per the process terms forming part of the claim are concerned, it is evident that the appellants use aqueous sodium hypochlorite as an oxidizing agent whereas the respondents use oxone. The difference between the two oxidizing agents was sought to be explained by the following diagram: -

	Oxone [$KHSO_5$]	Sodium hypochlorite [NaOCl]
		
Cas Number	100058-23-8	14380-61-1
Na,e	Potassium peroxymonosulfate	Sodium hypochlorite
M. Wt.	152.2 g/mol	74.44 g/mol
Appearance	Off-white solid	Yellow solution
Oxidant	Sulfur containing oxidizing agent	Chlorine containing oxidizing agent

74. It was submitted that the use of sodium hypochlorite is in any case not an essential element of the invention. It was submitted by Mr. Nataraj that when a subject matter of an invention is disclosed in the complete specification and the same has not been claimed, it would be deemed to have been dedicated to the public and courts would not allow the patentee to capture the disclaimed subject matter. Reliance in this respect was placed on the decision rendered by a learned Judge of the Court in **Boehringer Ingelheim Pharma GMBH & Co. KG vs. Vee Excel Drugs and Pharmaceuticals Private Ltd. & Ors.**[26] and which had adopted the dedication disclosure doctrine.

75. Mr. Nataraj also questioned the correctness of the submission of novelty being established pursuant to allocation of INN**.** It was contended that an INN which is allocated by the WHO is in no way concerned with novelty of an invention. It was submitted that since patent law is territorial, no international organization can be assumed or recognized to have the power or authority to determine novelty.

[26] 2023 SCC OnLine Del 1889

76. Insofar as the guidelines framed by the IPO were concerned, it was submitted the same are relevant only for Controllers and the prosecution of applications before those authorities and can have no bearing on infringement proceedings. It was submitted that the criteria of patentability and which may be relevant during the prosecution of a patent application cannot be imported to infringement proceedings. The submissions addressed on this score principally proceeded on lines identical to those propounded by the US Federal Court in *Atlantic Thermoplastics* and *Abbott Laboratories***.**

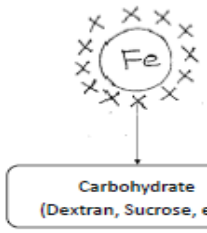
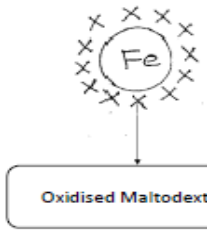
77. Mr. Nataraj submitted that while the appellants had laid great emphasis on the ruling of the EPO Opposition Board, the same is clearly of no relevance since it pertained to opposition proceedings initiated in respect of EP 2278204, the divisional emanating out of EP 1554315 which corresponded to the suit patent. It was his submission that the aforenoted decision was not rendered in the context of EP 1554315, which was the European equivalent of the suit patent but one rendered in the context of the divisional application which claimed a product and not a product-by-process. It was submitted that if EP 1554315 or even the suit patent had embodied a product, there would have existed no compulsion for the appellants filing the divisional applications.

E. ARGUMENTS OF CORONA REMEDIES

78. Appearing for Corona Remedies, Ms. Rajeshwari addressed the following submissions. Learned counsel submitted that the assertion of the appellant that the product claimed in Claim 1 has been granted the INN FCM is wholly incorrect since it is the case of the appellant in the patent application itself that the oxidation process constituted the crux

and differentiating factor between the prior art and the invention. Ms. Rajeshwari pointed out that the appellants had at more than one place asserted that it is the use of oxidized maltodextrin that imparts advantages of low toxicity and avoiding situations of anaphylactic shocks. The oxidation step, therefore, according to Ms. Rajeshwari, cannot be ignored during claim construction. Learned counsel submitted that the novelty of the product is acquired only with the aid and assistance of the step of oxidation. In view of the above, she would contend that what was novel was "iron carbohydrate complex with an oxidized maltodextrin".

79. According to Ms. Rajeshwari, the word oxidized must necessarily take colour from the process of oxidation. Ms. Rajeshwari also sought to explain the aforesaid by way of the following chart: -

S no	**Claim**	**Diagrammatic representation**	**Comparable prior art**
1	Water soluble iron carbohydrate complexes … having average molecular weight 80-400kda Or Ferric carbohydrate (redrafted claim)		Iron dextran …266 Kda Iron sucrose …43kda (*admittedly not novel – pg. 167-PI- Vifor v. MSN*)
2	Water soluble iron carbohydrate complexes obtainable from ☐ aqueous solution of iron salt, and ☐ the oxidation product of at least one maltodextrin and an aqueous hypochlorite solution at an alkaline pH, wherein, when one maltodextrin is present, the maltodextrin has a dextrose equivalent of between 5 and 20…….. (i.e ferric carboxymaltose-redrafted claim)		no prior art found by Patent office

80. According to learned counsel, the aforesaid would clearly establish that iron carbohydrate complexes were not novel and was merely the outcome of the process adopted by the appellants. Learned counsel then argued that even if the claim were to be liberally construed, the usage of the word oxidized would carry with it the process encumbrance as emphasized and highlighted in *Hospira UK Limited*. The submission, in essence was that the only novelty or inventiveness was contained in the process which was adopted. According to learned counsel, the learned Single Judge thus rightly came to conclude in paragraph 71 that the claim is essentially a product-by-process claim and thus limited and encumbered by the process in light of the principles enunciated in *Atlantic Thermoplastics* and *Abbott Laboratories***.**

81. Insofar as the product of Corona Remedies is concerned, Ms. Rajeshwari laid emphasis on what she asserted was an undisputable fact, namely, its product having a shell composed of hydrolyzed starch instead of maltodextrin. Learned counsel laid emphasis on the fact that as per the specifications and claims of the appellant maltodextrin ought to have a DE value of 5-20. As per the laboratory reports which have been placed on the record, the DE value of the respondent's starch was found to be between 25-27. This in itself, according to learned counsel, demolishes the charge of infringement. Learned counsel also referred to technical references which formed part of the record to contend that those reports had found that the DE value of starch would fall in the range of 5-20 whereas the DE value of hydrolyzed starch would always be more than 20. All of the aforesaid material, Ms. Rajeshwari contended, had never been questioned or assailed by the appellants. It

was submitted that Corona Remedies had been granted a patent for their product obtained by a different process which was never challenged at the pre grant stage by the appellants. It was submitted that although IN'536 was cited by the IPO, a patent ultimately came to be granted in favor of Corona Remedies and thus validating its stand.

82. Insofar as the INN question is concerned, it was her submission that INN is a generic and common word meant to be used by members of the public during the entire life of the product. It was submitted that FCM is a generic name and any carbohydrate product that contains iron, carboxy bonds and two units of sugar which would be maltose would fall within this category. It was her submission that the product of Corona Remedies contains starch and not maltodextrin, which is made up of two glucose units i.e. maltose and is oxidized. Her submission was that since the respondent's product is made up of a carbohydrate, namely starch, it has to necessarily be called FCM. In conclusion, it was her submission that the appellant has failed to dislodge the evident fact that the claim contains a process element and which relates to the oxidation of maltodextrin. In view of the above, it was her submission that the protection that could be claimed by the appellant would stand restricted to process elements alone.

F. INTERVENORS' STAND

83. Appearing for the intervener Mr. Lall, learned senior counsel at the outset submitted that the Act essentially contemplates claims either to a product or a process for preparing a product. According to Mr. Lall product-by-process constitutes a third type of claim, where the product is tied to or defined by its process of manufacture and which is granted rarely. According to Mr. Lall, the claims of the appellants and a

reading thereof would establish that its essence lies in a product prepared by a specific process and not the product per se. According to learned senior counsel this is exactly what the inventors sought to convey when the specification for the suit patent was drawn. This would also be evident, according to Mr. Lall, from the specification at more than one place alluding to FCM being distinguishable from the prior art which included dextrin-based complexes. Mr. Lall in this regard laid special emphasis on the following parts of the specification:

> "The problem to be solved by the present invention is to provide an iron preparation which is especially to be applied parentally and which can easily be sterilized,· ....
>
> In accordance with the present invention, the problem can be solved by providing iron (III) carbohydrate complexes on the basis of oxidation products of maltodetrin. ...
>
> The further object of the present invention is a process for producing the iron carbohydrate complexes according to the invention wherein one or more maltodextrins are oxidized. ...
>
> The iron content of the obtained iron (III) carbohydrate complexes is, for example, 10-40% w/w, especially, 20-30% w/w. They can easily be dissolved in water…"

84. It was further argued that during the prosecution of the suit patent, the Controller itself had raised objections with regard to novelty and inventive attributes of FCM. In response to those objections, it was pointed out, the appellants had themselves asserted that the essence of the invention lies in selecting maltodextrins and oxidizing the same. Mr. Lall specifically referred to the following paragraphs which formed part of the response that was submitted by the appellants before the Controller:

> "The essence of the present invention is that by appropriately selecting suitable maltodextrins having the specific dextrose equivalent as defined in the claims and by oxidizing them stereo selectively and region selectively at the terminal aldehyde group and then by reacting them with Fe (III) salts. Iron (III) - oxidized

> maltodextrin complexes are obtained, which are polynuclear complexes having a specific high molecular weight ...
>
> … The claim complexes are novel in view of the teachings since they are maltodextrin complexes and not dextran complexes. It has to be noted that by the reaction described in (b), maltodextrins cannot be obtained, and thus the compounds are completely different from the claimed complexes.
>
> ....The essence of the invention is that with the oxidized maltodextrin suitable iron (111) complexes can be obtained which has surprisingly good properties as mentioned below... "

85. In view of the aforesaid, it was argued that the suit patent does not represent a product claim and is merely a product derived from a specified process. According to learned senior counsel, insofar as product-by-process claims are concerned, such claims are deemed to be novel and inventive solely on account of the characteristics and feature imparted by the process and such claims are never construed as product claims since they are inextricably linked to the process of which they are an outcome. It was in the aforesaid light that Mr. Lall contended that the appellants could allege infringement only if they had been able to establish that the product manufactured by the respondents is obtained by the same process as claimed in the suit patent.

86. A reading of Claim 1 according to Mr. Lall would evidence that the process for obtaining water-soluble carbohydrate complexes comprised of the following steps:

(a) Reacting aqueous solution of an iron (III) salt with an aqueous solution of oxidized maltodextrins;

(b) The maltodextrin IS oxidized using hypochlorite solution in alkaline pH; and

(c) The maltodextrins IS characterized by when a single maltodextrin is used, the DE of the maltodextrin is in the range

of 5 to 20.

87. According to Mr. Lall, the aforesaid characteristics constitute the boundaries of the claimed subject matter. It was contended that claims which fall in the genre of product-by-process would be infringed only when the process of the claim is practiced and not otherwise. In support of his aforenoted submissions Mr. Lall relied upon the following passages as are found in the seminal work of **Terrell on the Law of Patents 18th Edition**:

> "**9-307**
> Accordingly, in the context of infringement, where a product is said to be "obtained by process X" it must have been actually obtained by that process in order to infringe. However, when it comes to validity (specially novelty), the wording "obtained by" does not exclude prior art material which is physically the same, even though it has not been obtained by the process claimed. In this respect therefore, though stated as a rule of novelty, the rule construes the words "obtained by" differently in the context of validity and infringement.
>
> **9-308**
> In the former case, it is not required that the prior art material is actually *obtained by* the process in order to deprive the claim of novelty, although in the latter case the product must be *obtained by* the process in order to infringe. While this contradicts the general rule that the construction of words used should be the same for validity and infringement, it is the only way to rationalize the decision reached in the House *of* Lords in *Kirin-Amgen* in which prior art material which had not been obtained by the claimed process was held to anticipate the claim which, in turn, is based on the EPO's case law on product-by-process claims."

88. According to Mr. Lall where a product claim describes the product solely in terms of the process, any product not made by a replication of that process cannot be deemed to infringe the claim. It was his submission that the process in a product-by-process claim acts as a limitation in infringement proceedings. Apart from the passages appearing in *Kirin Amgen* and *Abbott Laboratories*, Mr. Lall also

sought to draw sustenance from the following observations as appearing in *Atlantic Thermoplastics*:

> "This court, in its initial consideration of a product-by-process claim for patentability, acknowledged that process claim limitations define the product:
>
> Product-by-process claims are not specifically discussed in the patent statute. The practice and governing law have developed in response to the need to enable an applicant to claim an otherwise patentable product that resists definition by other than the process by which it is made. For this reason, even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. In re Thorpe, 777 F.2d 695 , 697, 227 USPQ 964 , 966 (Fed.Cir.1985).
>
> The entire history of product-by-process claims suggests a ready explanation for the apparent difference of view about treatment of those claims during ex parte administrative proceedings and during litigation. This court already distinguishes treatment of claims for patentability before the PTO from treatment of claims for validity before the courts. In re Zletz, 893 F.2d 319 , 321, 13 USPQ2d 1320 , 1322 (Fed.Cir.1989). This court permits the PTO to give claims their broadest reasonable meaning when determining patentability. Id.; see also J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553 1566, 223 USPQ 1089 , 1098 (Fed.Cir.1984), cert. denied, 474 U.S. 822 , 106 S.Ct. 73 , 88 L.Ed.2d 60 (1985) . During litigation determining validity or infringement, however, this approach is inapplicable. Zletz, 893 F.2d at 321 ; DeGeorge v. Bernier, 768 F.2d 1318 , 1322 n. 2, 226 USPQ 758 , 761 n. 2 (Fed.Cir.1985). Rather the courts must consult the specification, prosecution history, prior art, and other claims to determine the proper construction of the claim language. See, e.g., Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.2d 1017 1021, 4 USPQ2d 1283 , 1286, 5 Fed.Cir. (T) 129 (1987). Thus, accommodating the demands of the administrative process and recognizing the capabilities of the trial courts, this court treats claims differently for patentability as opposed to validity and infringement. The PTO's treatment of product-by-process claims as a product claim for patentability is consistent with policies giving claims their broadest reasonable interpretation. The same rule, however, does not apply in validity and infringement litigation. In any event, claims mean the same for infringement and validity. See, e.g., Senmed, Inc. v. Richard-Allan Medical Indus., 888 F.2d 815 , 818 n. 7, 12 USPQ2d 1508 , 1511 n. 7 (Fed.Cir.1989); Kimberly-Clark Corp.

v. Johnson & Johnson, 745 F.2d 1437 , 223 USPQ 603 (Fed.Cir.1984) .

Moreover, accepting Atlantic's invitation to ignore the process limitations in the '204 patent's product-by-process claims would require this court to disregard several other mainstay patent doctrines. For instance, Atlantic in effect invites this court to discount the significance of excluding claim limitations from infringement analysis. See, e.g., Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405 , 419, 28 S.Ct. 748 , 751, 52 L.Ed. 1122 (1908) ("[T]he claims measure the invention."). This court has repeatedly stated that infringement requires the presence of every claim limitation or its equivalent. See Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931 , 935, 4 USPQ2d 1737 , 1739-40 (Fed.Cir.1987) (in banc), cert. denied, 485 U.S. 961 , 108 S.Ct. 1226 , 99 L.Ed.2d 426 , cert. denied, 485 U.S. 1009 , 108 S.Ct. 1474 , 99 L.Ed.2d 703 (1988) ; Perkin-Elmer Corp. v. Westinghouse Elec., 822 F.2d 1528 1533, 3 USPQ2d 1321 , 1325 (Fed.Cir.1987); Lemelson v. United States, 752 F.2d 1538 1551, 224 USPQ 526 , 533 (Fed.Cir.1985). An accused infringer can avoid infringement by showing that the accused device lacks even a single claim limitation. See, e.g., Corning Glass Works v. Sumitomo Elec. U.S.A., 868 F.2d 1251 1259, 9 USPQ2d 1962 , 1968 (Fed.Cir.1989). Thus, ignoring the claim limits of a product-by-process claim would clash directly with basic patent principles enunciated by the Supreme Court and this court.

In addition, Atlantic's invitation to disregard the claim limitations also would require this court to determine infringement by comparing an accused product with an embodiment of the claims, not the claims themselves. This court has repeatedly emphasized that infringement analysis compares the accused product with the patent claims, not an embodiment of the claims. See, e.g., Datascope Corp. v. SMEC, Inc., 879 F.2d 820 , 824, 11 USPQ2d 1321 , 1323 (Fed.Cir.1989); SRI Int'l, 775 F.2d at 1121 ; Intervet Am. v. Kee-Vet Labs., 887 F.2d 1050 1055, 12 USPQ2d 1474 , 1478 (Fed.Cir.1989). Thus, Atlantic's invitation would require this court to directly ignore basic patent principles.

In light of Supreme Court caselaw and the history of product-by-process claims, this court acknowledges that infringement analysis proceeds with reference to the patent claims. Thus, process terms in product-by-process claims serve as limitations in determining infringement.

In so holding, this court acknowledges that it has in effect recognized another reason to regard product-by-process claims as exceptional. This court recognizes that product-by-process

> claims will receive different treatment for administrative patentability determinations than for judicial infringement determinations. This difference originated with the Supreme Court's BASF rules--a difference this court endorsed as recently as 1985. See Thorpe, 777 F.2d at 697 .
>
> This court, therefore, rejects Atlantic's invitation to ignore the process limitations in its product-by-process claims. This court's infringement rules do not require reversal of the district court's non-infringement finding regarding the Sorbothane process. Neither does this court disturb the PTO's present practice for assessing patentability of product-by-process claims."

89. According to Mr. Lall since the process adopted by BDR-the intervener is entirely different from that claimed by the suit patent, it cannot be said to be infringing. It was submitted that the process of oxidation of maltodextrins is carried out by the usage of hydrogen peroxide at acidic pH and reaction of iron salt with oxidized maltodextrin is carried out. The aforesaid two distinctive features of the process employed by BDR, according to Mr. Lall, clearly frees the intervener from the boundaries created by the suit patent.

90. Notwithstanding the above, Mr. Lall submitted that the practice of granting a product-by-process patent was developed principally to enable an applicant to claim an otherwise patentable product that resists definition and the only way to define it being through the process by which it is made. According to Mr. Lall this principle constitutes the solitary justification for permitting a product-by-process patent.

91. According to Mr. Lall, the appellants were not justified in obtaining a product-by-process patent since undisputedly they themselves have described the chemical formula of FCM in their application for obtaining an INN as far back as in 2006 and thus prior to the grant of the suit patent in 2008. Further, contrary to the procedure adopted in the EU and the US, Mr. Lall pointed out that the

appellants chose not to move any divisional applications before the IPO. It was submitted that the appellants had ample opportunity to amend the suit patent before its grant and thus claim a product patent in unambiguous terms. However, and since they failed to follow that process, the only logical conclusion would be that the process terms must be read as a limitation to the monopoly claimed by the appellant.

92. Insofar as the issues of claim construction are concerned, Mr. Lall referred to the provisions comprised in Section 10(4) of the Act and submitted that the patent specification must be read alongside the claims and not in isolation. In support of the aforesaid contention Mr. Lall relied upon the following principles as appearing in paragraph 30 of **Sotefin SA vs. Indraprastha Cancer Society and Research Center & Ors.**[27] :-

> "**30.** Claims define the scope of the invention, for which protection is claimed by a patentee. As per Section 10(4) of the Act, specifications of a patent should fully and particularly describe the invention. The specifications should disclose the invention and support the features narrated in the claims. The construction of a claim has to be done as a whole, to determine its true scope and to give it an effective meaning. The specifications which describe the invention have to be read from the point of view of the notional person acquainted with the language of the patent claim."

93. Learned senior counsel submitted that the appellants are required to fully and particularly describe their invention through the specification of the suit patent as well as the claims. This according to Mr. Lall clearly flows from a reading of Section 10(4)(a). It was also his submission that Section 10(4)(c) stipulates and prescribes that the claims would define the territory or scope of protection. This, according to learned senior counsel, is the indubitable position in law as

[27] 2002 SCC OnLine Del 516

enunciated in *F. Hoffmann-La Roche* and where the legal position was culled out as under:-

> **"67.** For the above conspectus, pithily put, principles of claim construction could be summarized as under:-
>
> (i) Claims define the territory or scope of protection (Section 10(4) (c) of the Patents Act, 1970.
>
> (ii) There is no limit to the number of claims except that after ten claims there is an additional fee per claim (1st Schedule of the Act).
>
> (iii) Claims can be independent or dependent.
>
> (iv) The broad structure of set of claims is an inverted pyramid with the broadest at the top and the narrowest at the bottom (Manual of Patents Office - Practice and procedure).
>
> (v) Patent laws of various countries lay down rules for drafting of claims and these rules are used by Courts while interpreting claims.
>
> (vi) One rule is that claims are a single sentence defining an invention or an inventive concept.
>
> (vii) Different claims define different embodiments of same inventive concept.
>
> (viii) The first claim is a parent or mother claim while remaining claims are referred to as subsidiary claims.
>
> (ix) If subsidiary claims contain an independent inventive concept different from the main claim then the Patent office will insist on the filing of a divisional application.
>
> (x) Subject matter of claims can be product, substances, apparatus or articles; alternatively methods or process for producing said products etc. They may be formulations, mixtures of various substance including recipes. Dosage regimes or in some countries methods of use or treatment may also be claimed.
>
> (xi) Where claims are 'dependent' it incorporates by reference 'everything in the parent claim, and adds some further statement, limitations or restrictions'. (Landis on Mechanics of Patent Claim Drafting).
>
> (xii) Where claims are 'independent' although relating to the same inventive concept this implies that the 'independent claim stands alone, includes all its necessary limitations, and is not dependent upon and does not include limitations from any other claim to make it complete …. An independent Claim can be the

> broadest scope claim. It has fewer limitations than any dependent claim which is dependent upon it'. (Landis on Mechanics of Patent Claim Drafting)
>
> (xiii) For someone wishing to invalidate a patent the said person must invalidate each claim separately and independently as it is quite likely that some claims may be valid even while some are invalid.
>
> (xiv) At the beginning of an infringement action the Courts in the United States conduct what is known as a 'Markman hearing' to define the scope of the claims or to throw light on certain ambiguous terms used in the claims. Although this is not technically done in India but functionally most Judges will resort to a similar exercise in trying to understand the scope and meaning of the claims including its terms."

In view of the above Mr. Lall contended that the appellants cannot extend protection beyond the disclosures made by them in the claims. According to learned senior counsel once the aforesaid principles are borne in mind, it would be manifest that the learned Single Judge has correctly come to conclude that tested on the anvil of claim construction the appellants can only claim exclusivity to the process.

94. It was then submitted that the treatment of product-by-process claims in the course of infringement analysis must be tested on principles distinct from those which may be applicable at the stage of considering patentability. According to learned senior counsel, in infringement proceedings the question which stands raised is not whether the product is novel or not but whether the product has been claimed. According to Mr. Lall, if the product accused of infringement has not been claimed, then no protection can be asserted by the appellants. It is in the aforesaid context that Mr. Lall submitted that factors relevant to adjudge patentability are immaterial for assessing infringement. Insofar as these issues are concerned Mr. Lall also laid

emphasis on the principles enunciated in *Atlantic Thermoplastics* and *Abbott Laboratories*. Mr. Lall reiterated that in the case of a product-by-process patent, the process is married to the product and thus the position in India would be the same as that was found by the US Courts in the decisions aforenoted. Mr. Lall further submitted that at the stage of infringement proceedings the Court's focus is solely on whether the product is anticipated by an existing prior art that does not follow the process limitation given in the claim. According to Mr. Lall a product-by-process patent differentiates the claimed product from the prior art based on the features or characteristics imparted to that product by the process or method claimed therein.

95. Mr. Lall also questioned the entitlement of the appellants to the grant of injunctive relief on principles of prosecution history estoppel and acquiescence. According to learned senior counsel, the learned Single Judge has taken note of the stand as struck before the Controller where on more than one occasion the appellants had conceded that Claim 1 related to a process claim. According to Mr. Lall the appellants cannot be permitted to approbate and reprobate and prosecution history estoppel clearly binds them.

96. Insofar as the interim orders passed in various suit proceedings were concerned it was submitted by Mr. Lall that the appellants had on more than one occasion conceded that the suit patent is a product-by-process patent. This according to learned senior counsel is manifest from the following contentions which were advanced by the appellants in those proceedings:

Sr. No.	Case Details	Extracts	Reference

1	**CS (OS) 4083/2014** Vifor (International) Ltd. vs. Mr. Dharmendra Vora & Anr.	*"4. It is the contention of the Plaintiff that they are the registered proprietor of Indian Patent No. 221536 (hereinafter referred to as IN'536). It is contended that the patent in the suit is related to a "product-by-process" invention which is a novel water-soluble iron carbohydrate complex which is a complex of iron (ferric) and oxidation product of one or more maltodextrins and a process for making the same. It is contended that the invention is used for intravenous treatment of iron deficiency. The properties of the complex makes high dosing up to 1000 mg iron, which characteristics make the said invention the first non-dextran iron complex for high intravenous (I. V) iron dosing."*	Judgment dated 07.11.2017 Annx. 9 @ PDF Pgs. 954– 955 FAO 159
2	**CS (Comm) No.1548/2016** Vifor (International) Ltd. vs. G. Sanu Nair & Ors.	*"10. The counsel for the plaintiff further states that the subject patent is not a process patent but a product by process patent" i.e., the product cannot be achieved without following the process in which the plaintiff has a patent, and the patent is in the product as well as the process."*	Order dated 24.11.2016 Annx. 9 @ PDF Pgs. 996 FAO 159
3	**CS (Comm) 261/2021** Vifor International Ltd. & Anr.	*"21. The main independent claim of the suit patent, claim 1, is a product claim for*	Annx. 5 @PDF Pg. No. 347 FAO 159

	vs. MSN Laboratories Private Limited & Anr.	*FERRIC CARBOXYMALTOSE, and can also be described as a "product-by-process" claim pursuant to a common practice in claim drafting since instead of using product characteristics, it was considered easier to describe the actual patented product using process terms. These are process elements which are used as an aid to help describe the end product which forms the subject matter of the claim, but these process elements are not limiting, and thus what is claimed is the product irrespective of the process used for its manufacture.*"	
4	**CS (Comm) 265/2021** Vifor International Ltd. & Anr. vs. Dr. Reddy's Laboratories Limited	"*21. The main independent claim of the suit patent, claim l, is a product claim for FERRIC CARBOXYMALTOSE, and can also be described as a "product-by-process" claim pursuant to a common practice in claim drafting since instead of using product characteristics, it was considered easier to describe the actual patented product using process terms. These are process elements which are used as an aid to help describe the end*	Annx. 5 @PDF Pg. No. 345 FAO 161

		product which forms the subject matter of the claim, but these process elements are not limiting, and thus what is claimed is the product irrespective of the process used for its manufacture."	

G. PRIOR INTERIM ORDERS AND OTHER ANCILIARY ISSUES

97. Before proceeding to deal with the principal questions which are raised, we deem it apposite to take note of some of the orders, interim as well as final, which were referred to and relied upon by the appellants before the learned Single Judge. As is evident from the chart which stands extracted in paragraph 26 of the impugned judgment, apart from the various interim injunctions which operated, the appellants had also referred to judgments and orders in terms of which suits had come to be finally decreed and permanent injunctions granted. We take note of the order dated 12 April 2018 passed in CS(COMM) 712/2018 as an exemplar of such an instance. Of equal significance is the order dated 07 November 2017 passed in CS(OS) 4083/2014. In our considered opinion, the mere fact that some of the aforenoted decrees came to be rendered ex parte would not detract from those orders being of relevance and significance insofar as the grant of interim injunction is concerned. Interim injunctions though not strictly binding precedents, constitute material of relevance when a prayer for interim injunction in respect of the same product comes to be laid. While granting or refusing to grant injunction in infringement actions, courts should not be selective and if choosing to refuse injunction, ensuring that adequate grounds are disclosed and which would indicate

why the views expressed or taken in the earlier orders are not liable to be followed. All that we seek to emphasize is that the aspects of certainty and court's adopting a uniform approach commend due consideration. Notwithstanding the above, we find that insofar as the instant appeal is concerned the learned Single Judge has evaluated and adjudged the issues which arose in great detail and thus the judgment cannot be faulted on this score.

98. We at the outset note that the prefatory parts of the impugned judgment proceed on the premise that it was the appellants' case that product-by-process claims are an unknown concept in Indian Patent law. This is evident from the following observations as entered by the learned Judge in paragraph 56:

> "**56.** Consistent stand adopted on behalf of Vifor during the arguments that the concept of 'product-by-process' claim is unknown to the statute and practice of 'patents' in India also stands negated by the observations of the Co-ordinate Bench of this Court in ***Nippon A&L Inc. v. Controller of Patents, 2022 SCC OnLine Del 1909,*** *albeit* in the context of amendment of product-by-process claim to a pure process claim."

99. The aforesaid understanding of the case set up by the appellant clearly appears to be factually incorrect when one views the averments which were made in the plaint. We deem it apposite to extract the following passages from the plaint which was filed in the suit:

> "**21.** The main independent claim of the suit patent, claim 1, is a product claim for FERRIC CARBOXYMAL TOSE, and can also be described as a "product-by-process" claim pursuant to a common practice in claim drafting since instead of using product characteristics, it was considered easier to describe the actual patented product using process terms. These are process elements which are used as an aid to help describe the end product which forms the subject matter of the claim, but these process elements are not limiting, and thus what is claimed is the product irrespective of the process used for its manufacture. The claim 1 therefore claims a product per se (i.e. FERRIC

CARBOXYMALTOSE), even if the same is prepared using an alternate process. This is further clear from the title of the suit patent, the opening words of the claim 1, and its contrast with the process claims 2-6, the contents of the complete specification, particularly the background and prior art, the problem statement as well as the solution provided by the suit patent.

22. In the "product by process" format of drafting patent claims, which is a well accepted practice under Indian patent law as well as in all major foreign jurisdictions, process terms are used to identify and describe the novel and unobvious product being claimed, without limiting the scope of the claim to said process terms. The suit patent comprises an independent product claim [claim 1 of the suit patent] in addition to the dependent claims, some of which are directed to the process to prepare the product as claimed in claim I. At the filing date of the application in respect of the suit patent in 2003, it was not easy for the applicant to describe, entirely in terms of its structural characteristics, the novel and unobvious product, FERRIC CARBOXYMAL TOSE, claimed in claim 1. While the process terms used in claim 1 to describe the product represent an exemplary process which may be used to prepare said product, it does not limit the claim to mandate the use of said process to prepare said product, and covers the product per se regardless of the process used for its preparation.

23. The aforesaid position is also supported by the practice guidelines prescribed to be followed by the Indian Patent Office in prosecution of patent applications containing product-by-process claims. As per the Indian Patent Office, a product-by-process claim should disclose a novel and inventive product and the patentability in such claim cannot depend on the novelty and un-obviousness of the process limitation alone. Accordingly, the fact that the suit patent IN'536 containing a claim in the product-by-process format has been granted in India is evidence of the novelty, inventiveness and patentability of the product claimed therein, independent of the process limitations.

24. In essence, the suit patent distinctly claims the following subject matter:

a. A Product (along with its defined and distinct characteristics) (claims 1, 7-9)

b. A Process for preparing said product claimed in claim 1 (claims 2-6)

xxxx xxxx xxxx

26. The claim 1 of the suit patent would therefore be infringed by any person who manufactures, sells etc. a product having the

> attributes of the product claimed in said claim (i.e. FERRIC CARBOXYMAL TOSE), irrespective of the process used to prepare said product."

100. A plain reading of the assertions made by the appellant establishes that Claim 1 was in unambiguous terms described as a product claim and which could also be described as a product-by-process claim. The appellant had averred that Claim 1 was for a product per se even if the same is prepared using an alternate process. The appellant had proceeded to assert that the suit patent comprises of an independent product claim in addition to the dependent claims, some of which were directed towards the process to prepare the product as claimed. It was also their categorical assertion that at the time of filing the patent application, the appellants were not in a position to describe FCM in terms of its structural characteristics. It was in the aforesaid backdrop and settled claim drafting practices that they asserted that the process terms used in Claim 1 represented an exemplary process alone and would not limit the claim to merely the process recited for the purposes of producing FCM. It was the appellants who had laid reliance on the guidelines framed by the IPO insofar as product-by-process claims are concerned. The appellants had contended that the suit patent comprises of a product as defined by Claims 1, 7 & 9 and a process for preparing that product as per Claims 2-6.

101. A reading of the plaint allegations would further establish the appellants having also relied upon the findings returned by the EPO for the divisional patent which was moved in order to buttress their contention of the suit patent being a product-by-process claim. Of equal significance were the averments made in para 26 of the plaint when the appellant had asserted that the suit patent would be infringed

by any person who manufactures or sells a product having attributes identical to that claimed by FCM irrespective of the process used to prepare.

102. All of the above clearly constrains us to observe that the learned Single Judge clearly appears to have misconstrued and failed to appreciate the essence of the stand as was taken by the appellants. The averments in the plaint, the reliance placed on the IPO guidelines, as well as the orders passed by the EPO, all unerringly tend to indicate and establish the appellant having placed FCM in the category of a product-by-process patent. The aforesaid stand would clearly be incompatible with the understanding of the learned Single Judge that the appellant sought to assert that product-by-process claims are an unknown concept in Indian Patent law.

H. SCOPE OF PRODUCT-BY-PROCESS

103. The learned Single Judge in para 60 then took the position that a product claim must be described by its composition and structure, both physical and chemical, and thus not limited by a process. The Court has in this respect observed thus:

> "…It is not Vifor's claim that IN'536 is a process claim. To be categorised as a product claim, a product must be described by its composition and structure, both physical and chemical and not limited by a process. Claim 1 does not fit into the definition of 'product claim' and the limitations on obtaining FCM by a specified process defined in the said claim aligns it with a 'product-by-process claim…'

104. It is thus manifest and evident that the learned Single Judge appears to have taken the position at the very outset that the specified processes defined in a claim act as limitations and thus patent protection being liable to operate only insofar as the claimed process

was concerned. As we read the impugned judgement, we find that the learned Single Judge appears to have taken the principled position that product and process claims operate in distinct silos and thus losing sight of the undisputed fact that an amalgam of the two, and which broadly speaking represents what product-by-process claims essentially are, cannot be countenanced.

105. The understanding of the learned Judge of process terms being limiting is then set out in the following parts of the impugned judgment:

> "**55.** Addressing the first issue first, reference be made to the *'Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*' issued by the Office of the Controller General of Patents, Designs and Trademarks in October, 2014, more particularly, paragraph 7 thereof, wherein there is a reference to an IPAB order in the ***Research Foundation of State University of New York v. Assistant Controller of Patents, [OA/11/2009/PT/DEL].*** These Guidelines indicate that the Patent Office in India recognises the existence of product-by-process claims and this concept is not alien to the patent jurisdiction in India, else it would not have laid down the pre-requisites for assessment of novelty for product-by-process claims. Patentability of product-by-process claim depends upon the product itself if it does not depend upon the method of production, which highlights that process terms in such claims are limitations and not additional features of the product concerned though it must be stated that assessment of novelty and the assessment of infringement are separate exercises and cannot be equated….
>
> xxxx xxxx xxxx
>
> **66**. As captured above, preamble of Claim 1 recites 'water-soluble iron carbohydrate complexes' and 'obtainable from' is the transition phrase. The limitations to the preamble are expressed in the form of process terms. The process is limited by the requirement of using an aqueous solution of iron (III) salt and an aqueous solution of oxidation product of one or more maltodextrins using an aqueous hypochlorite solution at a pH-value within the alkaline range. This process is further limited by specifying that where one maltodextrin is applied, its DE value lies between 5 and 20 and when a mixture of several maltodextrins is applied, DE value of the mixture lies between 5 and 20 and the DE value of each individual maltodextrin

> contained in the mixture lies between 2 and 40. The process so claimed results in iron carbohydrate complexes with a defined average molecular weight between the range 80 kDa to 400 kDa.
> **67.** Claim 1 thus refers to the product followed by description of the sequence of using aqueous solution of oxidation product of one or more maltodextrins in an alkaline pH in the presence of a specified oxidizing agent i.e. aqueous hypochlorite solution, where the end product i.e. iron carbohydrate complexes have a defined average molecular weight and the limitation to the product by the process is *prima facie* evident. Stand of Vifor that the claim as drafted is a product claim and/or that even with the limitation of the process, the claim leads to a product claim only, would render the description of the claim with a detailed and a specific process meaningless and *otiose.* Therefore, *prima facie* IN'536 is a product-by-process claim and monopoly will be limited to the product obtained by the specific process in the claims, going by the first principles delineated in ***F. Hoffmann-La Roche Ltd. & Anr. (supra),*** that claims define the territory or scope of protection."

106. The issues which thus stand crystallized for our consideration and emerge to the fore are primarily the following. The impugned judgment is foundationally premised firstly on the suit patent being a product-by-process claim. The second principle which weaves through the entire judgment is of process terms limiting the scope of the claim and patent protection thus being extendable only to the process and not the product. We have already noticed that the learned Judge appears to have proceeded on the incorrect premise that the appellant had contended that the Indian patent regime did not recognize or contemplate product-by-process claims. This, as noted hereinbefore, appears to be factually incorrect in light of the expressed stand of the appellant in the suit as borne out from the plaint and the pleadings thereof. We are thus principally called upon to consider the scope of product-by-process claims and the extent of protection accorded by such patents.

107. The Act undoubtedly confers patent protection to both products as well as processes. This is evident not just from a plain reading of Section 48 of the Act but also the definition of invention in the statute. The fact that novelty and inventive characteristics or qualities are key attributes for a patent cannot possibly be doubted. Section 48(a) of the Act enables a product patentee to restrain a third party from making, using or selling that product. A person who holds a process patent is on the other hand empowered by the statute to restrain another from using that process as well as from making, using or selling a product obtained directly by that process. Thus, the Act acknowledges that both product as well as processes may be imbued with inventive qualities and thus be patentable.

108. In order to evaluate the correctness of this submission we firstly bear in mind the statutory position as embodied in Section 48 of the Act and which reads thus:

> "**48**. Rights of patentees.—Subject to the other provisions contained in this Act and the conditions specified in Section 47, a patent granted under this Act shall confer upon the patentee—
>
> (*a*) where the subject-matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;
>
> (*b*) where the subject-matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India"

109. A product-by-process claim on the other hand is an amalgam or a hybrid and one which "straddles" the otherwise discernible and recognized distinction between products and process patents per se. A

patent which falls in the category of product-by-process would be founded on a claim relating to a novel product whose unique attributes are sought to be explained by reference to its manufacturing process. Such a claim would embody manufacturing process terms to define the product. The learned Judge however appears to suggest that any claim which embodies process terms is one which pertains to a process alone and cannot possibly be recognised as referring or relatable to a product. This is apparent from the learned Judge in para 60 holding that a ***"product must be described by its composition and structure, both physical and chemical and not limited by a process"***. In the very same sentence, it is observed that limitations on obtaining FCM ***"by a specified process defined in the said claim aligns it with a 'product by process claim'."*** The Court then proceeds to hold in para 67 that IN'536 is a product-by-process claim and ***"….monopoly will be limited to the product obtained by the specific process in the claims…."***. In our considered opinion while the learned Judge was correct in recognizing IN'536 to be a product-by-process claim, the decision proceeds on the basis of certain fundamental fallacies.

110. As would be evident from the discussion which ensues, a product-by-process claim and the submission of claims in that format is neither unconventional nor unknown. In fact, it clearly appears to be an accepted and acknowledged method of claim drafting. This is apparent from the following passage which appears in **Ex Parte Painter**[28] a decision which was rendered as far back as in 1891: -

> "It requires no argument to establish the proposition that as a rule a claim for an article of manufacture should not be defined by the process of producing that article. On the other hand, when a man has made an invention his right to a patent for it, or his

[28]ExParte Painter, 57 O., G. 999 (Comm'r Pat. 1891)

> right to a claim properly defining it, is not to be determined by the limitations of the English language. When the case arises that an article of manufacture is a new thing, a useful thing, and embodies invention, and that article cannot be properly defined and discriminated from prior art otherwise than by reference to the process of producing it, a case is presented which constitutes an exception to the rule."

111. As would be manifest from the aforesaid observation appearing in that celebrated decision, product-by-process claims were accepted in situations where an article embodied an invention and yet could not be properly defined and discriminated from the prior art. It was the constraint of the claimed invention being incapable of being explained in precise terms that compelled the drafter to resort to referring to the process of manufacture. The aforesaid well settled practice in claim drafting is employed mainly in cases of complex drugs or chemical products and compounds and where the full structure of the product may defy expression in precise terms and thus compel the author to explain the extent of the invention by reference to process terms at the time of presentation of the patent application. Product-by-process claims appear to owe their genesis to cases where new products could not be fully described by their structure or where complex compounds defied precise explanation compelling the patent applicant to rely upon the process of manufacture. The construction of claims in that manner was a practise which came to be adopted with reference to chemical and biological products and in situations where at the time of filing of the patent application the complete structure of the product was either unknown or indefinable. The aforesaid acknowledged constraints led to Patent Offices and courts across the world propounding the "rule of necessity".

112. We note that the rule of necessity and the compulsions which

accompany the submission of a claim in product-by-process terms was accepted even in *Hospira UK Limited*. We deem it apposite to extract the following passages from that decision:

> "**135.**The EPO's approach to overt product by process claims today is settled. They will be permitted (and only permitted) if there is no other way of defining the product open to the patentee. This is a decision based on policy. Such claims present clarity problems and are best avoided but if there is no alternative way of defining the characteristic in question, then they will be permitted.
>
> **136.**But despite their apparently esoteric nature (even by the standards of patents) product by process language is actually quite common and hardly remarked upon. Claim 1 of628 as granted is a product claim which uses process language in an unexceptional way. The opening words are "*A formulation comprising a lyophilised mixture of…*".This is a claim to a product defined by reference to the process by which it has been made. Claims drafted this way are granted routinely and rarely raise any issue. No one calls these claims product by process claims and the EPO does not apply its case law to this language. That is why I referred to "overt" product by process claims in the previous paragraph.
>
> **140.**Therefore the ratio of the decision in ***Kirin-Amgen*** is that an identical product made by a new process does not count as new. In that respect the UK now follows the EPO. Lord Hoffmann did not agree with the Court of Appeal's decision but the focus of his disagreement was not about the EPO's rule of practice, the issue was that there was a point of law underpinning that practice. Lord Hoffmann was concerned to align the UK law of novelty with the law applied in the EPO. Beyond a need for a claim to be novel, he was not commenting on whether the EPO's practice was sound or not and did not comment on the Court of Appeal's refusal to follow it as a rule of practice only, subject to applying the correct law of novelty."

113. Closer to home the IPO Examination Guidelines and which were also noticed by the learned Single Judge while speaking of product-by-process claims lay down the following principles:

> **"7.9 Product-by-process claims:**
>
> A claim to a product obtained or produced by a process is anticipated by any prior disclosure of that particular product *per se*, regardless of its method of production. In a product-by-

process claim, by using only process terms, the applicant seeks rights to a product, not a process. The IPAB held in ORDER No. 200/2012 ".....product-by-process claims must also define a novel and unobvious product, and that its patentability cannot depend on the novelty and unobviousness of the process limitations alone. Therefore, the patentability of a product by process claim is based on the product itself if it does not depend on the method of production. In other words, if the product-by-process claim is the same as or obvious from a prior product, the claim is un-patentable even if the prior art product was made by a different process. Accordingly the product by process claim must define a novel and unobvious product and the patentability in such claim cannot depend on the novelty and un-obviousness of the process limitation alone" 4.Therefore, in product-by-process claims, the applicant has to show that the product defined in process terms, is not anticipated or rendered obvious by any prior art product. In other words the product must qualify for novelty and inventive step irrespective of the novelty or inventive step of the process."

114. The EPO while dealing with the subject has framed its own set of guidelines the relevant parts whereof are extracted hereunder: -

"**4.12 Product-by-process claim**

A claim defining a product in terms of a process is to be construed as a claim to the product as such. The technical content of the invention lies not in the process *per se*, but rather in the technical properties imparted to the product by the process. Claims defining plants or animals produced by a method including a technical step which imparts a technical feature to a product constitute an exception in so far as the requirements of Art. 53(b) as interpreted by Rule 28(2) are concerned. The exclusion under Rule 28(2) regarding plants and animals exclusively obtained by means of an essentially biological process does not apply to patents granted before 1 July 2017 nor to pending patent applications with a filing date and/or a priority date before 1 July 2017.

If a technical feature of a claimed plant or animal, e.g. a single nucleotide exchange in the genome, can be the result of both a technical intervention (e.g. directed mutagenesis) and an essentially biological process (a natural allele), a disclaimer is necessary to delimit the claimed subject-matter to the technically produced product (see examples in G-II, 5.4.2.1 and G-II, 5.4). If, on the other hand, the feature in question can unambiguously be obtained by technical intervention only, e.g. a

transgene, no disclaimer is necessary. For the general principles governing disclaimers see H-V, 4.1 and H-V, 4.2.

If the process through which the claimed plant or animal is defined does not impart identifiable and unambiguous technical features to the plant or animal, e.g. the genetic information present in the genome, the claim directed to a plant or animal lacks clarity.

Claims for products defined in terms of a process of manufacture are allowable only if the products as such fulfil the requirements for patentability, interalia that they are new and inventive, and it is impossible to define the claimed product other than in terms of a process of manufacture. A product is not rendered novel merely by the fact that it is produced by means of a new process. The claim may for instance take the form "Product X obtainable by process Y". Irrespective of whether the term "obtainable", "obtained", "directly obtained" or an equivalent wording is used in the product-by-process claim, it is still directed to the product *per se* and confers absolute protection upon the product.

As regards novelty, when a product is defined by its method of manufacture, the question to be answered is whether the product under consideration is identical to known products. The burden of proof for an allegedly distinguishing "product-by-process" feature lies with the applicant, who has to provide evidence that the modification of the process parameters results in another product, for example by showing that distinct differences exist in the properties of the products. Nevertheless, the division needs to furnish reasoned argumentation to support the alleged lack of novelty of a product-by-process claim, especially if this objection is contested by the applicant."

115. A similar position comes to the fore when one views the guidelines framed by the US PTO with reference to product-by-process claims:-

"2113 Product-by-Process Claims [R-07.2022]

I. PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does

not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolaccolor developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). Furthermore, "[b]ecause validity is determined based on the requirements of patentability, a patent is invalid if a product made by the process recited in a product-by-process claim is anticipated by or obvious from prior art products, even if those prior art products are made by different processes." Amgen Inc. v. F. Hoffmann-La Roche Ltd., 580 F.3d 1340, 1370 n 14, 92 USPQ2d 1289, 1312, n 14 (Fed. Cir. 2009). See also Purdue Pharma v. Epic Pharma, 811 F.3d 1345, 117 USPQ2d 1733 (Fed. Cir. 2016). However, in the context of an infringement analysis, a product-by-process claim is only infringed by a product made by the process recited in the claim. Id. at 1370 ("a product in the prior art made by a different process can anticipate a product-by-process claim, but an accused product made by a different process cannot infringe a product-by-process claim").

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations). See also In re Nordt Dev. Co., 881 F.3d 1371,1375-76, 125 USPQ2d 1817, 1820 (Fed. Cir. 2018)(holding "the specification demonstrates that 'injected molded' connotes an integral structure," and discussing several cases since Garnero that held "limitations to convey structure even when they also describe a process of manufacture").

II. ONCE A PRODUCT APPEARING TO BE

SUBSTANTIALLY IDENTICAL IS FOUND AND A PRIOR ART REJECTION IS MADE, THE BURDEN SHIFTS TO THE APPLICANT TO SHOW AN NONOBVIOUS DIFFERENCE

"The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an nonobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 799, 803, 218 USPQ 289, 292-33 (Fed. Cir. 1983) (The claims were directed to a zeolite manufactured by mixing together various inorganic materials in solution and heating the resultant gel to form a crystalline metal silicate essentially free of alkali metal. The prior art described a process of making a zeolite which, after ion exchange to remove alkali metal, appeared to be "essentially free of alkali metal." The court upheld the rejection because the applicant had not come forward with any evidence that the prior art was not "essentially free of alkali metal" and therefore a different and nonobvious product.).

See also Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (The prior art disclosed human nerve growth factor (b-NGF) isolated from human placental tissue. The claim was directed to b-NGF produced through genetic engineering techniques. The factor produced seemed to be substantially the same whether isolated from tissue or produced through genetic engineering. While the applicant questioned the purity of the prior art factor, no concrete evidence of an nonobvious difference was presented. The Board stated that the dispositive issue is whether the claimed factor exhibits any unexpected properties compared with the factor disclosed by the prior art. The Board further stated that the applicant should have made some comparison between the two factors to establish unexpected properties since the materials appeared to be identical or only slightly different.).

III. A REJECTION BASED ALTERNATIVELY ON 35 U.S.C. 102 OR 103 FOR PRODUCT-BY-PROCESS CLAIMS HAS BEEN APPROVED BY THE COURTS

"[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more

> difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Office personnel should note that reliance on the alternative grounds of 35 U.S.C. 102 or 35 U.S.C. 103 does not eliminate the need to explain both the anticipation and obviousness aspects of the rejections."

116. The IPO Guidelines lay emphasis on product-by-process claims being foundationally referable to a novel or unobvious product. It further goes on to significantly state that patentability of the product cannot depend upon the mere novelty of the process adopted. It thus proceeds to adopt the view expressed by the IPAB which in a verdict referred to in the guidelines held that if the claim be in respect of a product which was unpatentable, the same would not be sustainable merely because a different process was adopted. The IPO thus accords primacy upon the product comprised in the product-by-process claim not being anticipated or rendered obvious by any prior art. It proceeds further to pertinently observe that it is the product which must qualify the test of novelty irrespective of the inventive step of the process. The EPO expounds a similar position stating that the element of invention does not lie in the process but in the technical properties imparted to the product by that process. EPO restricts the admission of such claims only to such products which notwithstanding employment of process terms, otherwise fulfil the requirement of patentability. It thus takes the unequivocal position that it is the product which must be found to be

new and inventive and permits the submission of such claims only if it is impossible to define that product other than in terms of a process of manufacture. This is again reemphasised by the EPO when it states that a product claim which comprises of both product and process features must be founded on the novelty of the claimed product only and upon it being established that it has attributes and properties distinct from those known in the prior art. Similarly, the USPTO pertinently observed that while a product-by-process claim may be defined by the process, the determination of patentability is based on the product itself. It essentially takes a position identical to that propounded by the IPO and EPO namely, that the patentability of the product does not depend on the method of manufacture.

117. We also take note of the following extract as appearing in the work of **Cook** titled **'Pharmaceuticals, Bio-Technology and the Law' [Edition: 2016 through current]**:

> "**[5.21]**
>
> Patent claims are sometimes expressed as to 'product A obtained by process B'. This is a type of product claim known as a 'product by process' claim and so expressed should, for infringement purposes only, cover the product in question when produced by the claimed route. It is thus much more limited than a 'per se' claim to the product itself. In Europe, where countries have modelled their infringement law on the Community Patent Convention (and also in this respect the EPC),1 such a claim should provide little if any benefit over a process claim given that the direct product of a patented process would infringe a process claim, as explained below in relation to infringement.
>
> In the EPO, such claims will only be allowed if the products themselves are new, and a product is not to be regarded as novel merely because it is produced by a new process. The EPO Guidelines suggest that 'product by process' claims should take the form 'product X obtainable by process Y', making it clear that the product is covered by the claim even when not in fact produced by the process described in the claim, although in practice many 'obtained by' claims are still seen, and may be

interpreted in some jurisdictions as 'obtainable by'. There should be less need for such claims these days than there used to be, in view of modern analysis methods which should more readily allow novel substances to be defined by their structure and/or other characteristics in a traditionally drawn product claim.

Such provision is also now mandated by Article 28(1) of TRIPs, set out below at para 5.102.
UK practice used to differ by allowing claims to 'product A obtained by process B' where product A was not itself novel but the process B by which it was prepared was. However, in Kirin-Amgen v Transkaryotic Therapies [2004] UKHL 46, [2005] 1 All ER 667 (HL), the House of Lords held that the UK should follow the EPO practice and that a claim in such form to a protein made by recombinant DNA engineering lacked novelty over the same protein when isolated from natural sources and which formed part of the state of the art.

[5.22]

The EPO and English case law as to product by process claims was extensively reviewed in the English Patents Court in Hospira v Genentech No 2,1 starting with the observation (at [125]) that 'product by process claims are tricky' and concluding (at [147]) with the following principles derived from this analysis of such case law:

"(i) A new process which produces a product identical to an old product cannot confer novelty on that product. To be novel a product obtained or obtainable by a process has to have some novel attribute conferred on it by the process as compared to the known product.

(ii) This rule is a rule of the law of novelty. It is not a principle of claim construction. Although in effect the rule treats obtained by" language as "obtainable by" language, nevertheless as a matter of claim construction a claim to a product "obtained by" a process means what it says. That will be the relevant scope of the claim as far as infringement and sufficiency are concerned.

(iii) Although normally a patent is drafted by the inventor "in words of his own choosing", the EPO will not permit overt product by process language unless there is no other alternative available. By no other alternative, they mean no other way of defining a particular characteristic of the product in question."

In the course of this analysis the point was made that a claim may be a 'product by process' claim in effect even where the traditional language associated with such claims was lacking. Thus, in this case a claim to a 'lyophilised mixture' was held to

be such a claim, as it was limited to something which has actually been made by lyophilisation. It was observed that as the claim did not say 'obtainable by' lyophilisation, it was a claim to a product 'obtained by' lyophilisation, and thus whilst material having identical characteristics but which were not achieved by lyophilisation might anticipate such claim, such material could never infringe it."

118. Of equal significance are the following passages as appearing in the work of **'Roughton, Johnson and Cook on Patents' [Edition 2022 through current]** where while dealing with product-by-process claim it is observed:

"**Product by process and analogy process claims**
[2.102]
Under the old law, it was common to include what was known as a product-by-process claim. The purpose of the claim was to prohibit the use of known products created by a new process. The converse sort of claim, an analogy process claim, was common in German practice and involved a claim for the use of a known process to produce a new (unknown) product.

Practice at the European Patent Office
[2.103]
The EPO does not permit product-by-process claims, where the only reason for using that form of claim is to try to obtain protection for a known product. The rationale for not allowing such claims is that art 64(2) of the EPC provides protection for products derived by novel processes. The EPO will, however, accept a product-by-process claim in relation to structurally indefinable product inventions3 (that is where the product cannot be defined in any other way than by the way it is made) and a claim for a product made by a particular process is construed as a claim for the product itself. This approach suggests that the EPO does not see a clear distinction between things which are 'obtained by' and those which are 'obtainable by' – something which may be very significant in terms of infringement.

[2.104]

In contrast, the EPO does allow analogy process claims and has specifically held them to be patentable. It is not clear why this decision was reached and it seems somewhat inconsistent with the approach to product-by-process claims. A novel (and inventive) product produced by an analogy process can be

patented in its own right and there is no need to patent the known process for producing that product as the process of making that product would in itself be an infringing act. Accordingly, it is submitted that analogy process claims should be no more an acceptable form than product-by-process claims as the rationale equally applies to both types of invention."

119. **Terrel on Patent Law 19th Edition** contains the following instructive passages:

"**9-134** The different nature of these two types of claim is recognized by art.64(2) EPC which provides that:

> "If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process."

9-135 That article is given effect by PA 77 s.60(1)(c).

9-136 So far as a product claim is concerned, it will normally be infringed (or anticipated) if the device (or prior art) in question is capable of being used in a way falling within the claim, regardless of whether it in fact was, or indeed was ever intended to be, so used.

9-137 A product claim will cover the product wherever found. But if the claim, properly construed, is to an isolated product (e.g. an enantiomer) then it will not extend to the product when found in unseparated from (e.g. a racemate).

9-138 Process claims may require and refer to the presence of particular hardware in order to carry them out, as for example in Technip France SA's Patent, where Jacob LJ noted that:

> "It is an unusual claim structure, a process claim followed by a product-for-carrying-out-the-process claim. Moreover the process claim requires various items of hardware and is thus not 'pure process.' Nonetheless I do not think that the skilled man, to whom it is addressed, would have much difficulty in following it, guided as he will be by the drawings."

9-139 It is submitted that such claims remain process claims, albeit not "pure".

Product-by-process claims: "obtainable by"

9-140 Under its current practice, the EPO does not usually permit claims of the form "A [product]… obtained by the process of…" as such claims provide no protection over and above a process claim. Moreover a new process is not enough in itself to make the product new, for "it is still the same product even if made in a different way".

9-141 Prior to the decision in Hospira UK Ltd v Genentech Inc it was not clear whether this is merely a rule of novelty, or whether it is a rule of construction (namely, that the words "obtained by the process of" are to be disregarded as adding no further limitation).

9-142 The EPO does however in principle permit "A [product]… obtainable by the process of …' because looked at as a matter of language it is a product claim, and it takes the view that such claims are therefore to be assessed for the purpose of novelty, etc. As product claims, and the method actually used is irrelevant. The EPO Guidelines state:

> "Claims for products defined in terms of a process of manufacture are admissible only if the products as such fulfil the requirements for patentability, i.e. inter alia that they are new and inventive. A product is not rendered novel merely by the fact that it is produced by means of a new process (see T150/82, O.J. 7/1984, 309). A claim defining a product in the process is to be construed as a claim to the product as such and the claim should preferably take the form 'Product X obtainable by process Y', or any wording equivalent thereto, rather than 'Product X obtained by process Y'."

9-143 In some circumstances, this may provide useful and fair protection for inventors. Where there is a clearly defined class of products and a clear test for "obtainable by", a patentee who has such a claim can bring an action without having to establish the method of manufacture which an infringer actually used.

9-144 However, such claims give rise to serious problems of construction. If such a claim only covers products actually made by the processes taught in the specification, then it adds nothing. But if the claim is wider and covers products made by other processes, then questions arise as to how much wider, what test is to be applied in determining whether or not a product falls within the claim, and how skilled persons are to determine whether or not they infringe. These questions were addressed and answered in Hospira UK v Genentech.

9-145 Claim 1 of the Genentech patent was a claim to a product. The product was a lyophilized (i.e. freeze fried) formulation of the antibody trastuzumab comprising at least four ingredients: a lyoprotectant, buffer, surfactant and antibody. The product claimed in claim 1 of the patent had to be "obtainable by" lyophilizing the solution of Table 5 of the patent. Birss J explained that although most inventions are either products or processes there is no rule that an invention must either be one or the other. He explained that in the case of Swiss-form claims infringement is "often argued only under s.60(2) (infringement by supplying means essential) which avoids the problem of deciding whether it is a product or a process". He continued:

> "128. Another kind of claim which straddles the boundary between products and processes is a product by process claim. As a matter of language there are two kinds: (1) a product 'obtained by' a process, and (2) a product 'obtainable by' a process. At least at first sight they are different.
>
> 129. At first sight the scope of a claim to a product 'obtained by' a process would be only to products which had actually been made by the process. There might be problems of proof in an infringement case or for novelty but conceptually there is no difficulty. If no products had ever been made that way in the past, then the claim would be novel. The fact that such products are physically entirely identical to products made in the past would not alter the fact that no product made by that process had been made available to the public before. They would only be infringed by products actually made by the relevant process. This was the view taken of product by process claims in the Court of Appeal in Kirin Amgen ([2002] EWCA Civ 1096, [2003] R.P.C. 3)."

9-146 The judge pointed out that an issue not addressed in Kirin-Amgen was whether the rule that the process feature is irrelevant for novelty is a rule of the law of novelty or a rule of mandatory claim interpretation. He explained how in Kirin-Amgen the House of Lords had required, for the purposes of being novel, a claim to erythropoietin made by the expression of a gene in a host cell, to be different from known urinary erythropoietin. On the other hand, when the House of Lords decided that the defendant's rEPO did not infringe, it was because it was not the product of the expression of a gene in a host cell. Hence it was, as the judge put it, "applying the process feature as a relevant limitation which was not satisfied

for the purposes of (non-) infringement but ignoring it for the purposes of novelty". As he explained, that can only be on the basis that the product by process rule is a rule of novelty law, not claim construction. The paradoxical result is that a product not made by the claimed process had been found not to infringe because it was not made by that process while another product not made by that process was found to render the claim lacking novelty. When it comes to infringement however, Birss J considered that:

> "It is not obvious that an inventor who drafted his or her claim in the form of a product 'obtained by' a process ever intended to cover other things or would be understood to be using language to mean that. The test for novelty is one thing but to ignore the clear words of the claim may result in it covering things which owe nothing to the inventor's technical contribution and risk insufficiency. It is hard to see how one can apply one of the key principles of construction emphasized by Kirin-Amgen itself, that the reader considers what the draftsman was using language to mean, in any other way."

9-147 The judge derived the following principles from his consideration of the EPO and UK authorities:

> "i) A new process which produces a product identical to an old product cannot confer novelty on that product. To be novel a product obtained or obtainable by a process has to have some novel attribute conferred on it by the process as compared to the known product.
>
> ii) This rule is a rule of the law of novelty. It is not a principle of claim construction. Although in effect the rule treats 'obtained by' language as 'obtainable by' language, nevertheless as a matter of claim construction a claim to a product 'obtained by' a process means what it says. That will be the relevant scope of the claim as far as infringement and sufficiency are concerned.
>
> iii) Although normally a patent is drafted by the inventor 'in words of his own choosing', the EPO will not permit overt product by process language unless there is no other alternative available. By no other alternative, they mean no other way of defining a particular characteristic of the product in question."

> **9-148** Accordingly, in the context of infringement, where a product is said to be "obtained by process X" it must have been actually obtained by that process in order to infringe. However, when it comes to validity (specifically novelty), the wording "obtained by" does not exclude prior art material which is physically the same, even though it has not been obtained by the process claimed. In this respect therefore, though stated as a rule of novelty, the rule construes the words "obtained by" differently in the context of validity and infringement.
>
> **9-149** In the former case, it is not required that the prior art material is actually obtained by the process in order to deprive the claim of novelty, although in the latter case the product must be obtained by the process in order to infringe. While this contradicts the general rule that the construction of words used should be the same for validity and infringement, it is the only way to rationalize the decision reached in the House of Lords in Kirin-Amgen in which prior art material which had not been obtained by the claimed process was held to anticipate the claim which, in turn, is based on the EPO's case law on product-by-process claims."

120. The Board of Appeal in a decision rendered in **1998**[29] had this to say while discussing the scope of product-by-process claims:-

> "**4.2** There are basically two different types of claim, namely a claim to a physical entity, e.g. a product, and a claim to a physical activity, e.g. a process for preparing a product (see decisions G 2/88, OJ EPO 1990, 93, point 2.2. of the reasons; T 150/82, OJ EPO 1984, 309, point 7 of the reasons). These two basic types of claim are referred to as the two possible categories of claim. Therefore, the proposed amendment of the patent in suit as granted according to the main request consists in a change of the category of the claims, i.e. a switch from the category of a physical activity to the category of a physical entity.
>
> **4.3** Article 123 (3) EPC requires that the claims of a patent may not be amended during opposition proceedings in such a way as to extend the protection conferred. This applies to all amendments including the change of the category of claim. In order to decide whether or not the change of the category in the patent in suit satisfies that requirement, it is necessary to compare the protection conferred by the category of claim before amendment, i.e. as granted, with that of the new category

[29]T 0020/94 – 3.3.1 Enichem Synthesis S.p.A vs. Ciba Speciality Chemicals Holding Inc.

of claim after amendment (see decision G 2/88, loc cit., points 3.2. and 4.1 of the reasons).

4.3.1 The protection conferred by a claim directed to a process for preparing a product covers that process. Pursuant to Article 64 (2) EPC, the product insofar as it is directly obtained by that process, is also protected. Hence, the same product, when obtained by any other process for preparing the product, is not within the scope of protection conferred by the process claim. In the present case, the process claim as granted, i.e. before the amendment to a product claim, confers protection to the process claimed and, exclusively, to the particular tetrakis [3– (3, 5– di-tert. buty1-4-hydroxypheny1)–propiony1–oxymethy1] methane directly obtained by the claimed process; that particular tetrakis [3– (3, 5– di– tert. buty1–4–hydroxypheny1)–propiony1–oxymethy1] methane, when obtained by any other process, is not protected by the claims as granted.

4.3.2 The protection conferred by a claim directed to a product per se, however, is absolute upon such product. The product claim, thus, confers protection to that product regardless of the process by which it is prepared (see decisions G 2/88, loc cit., point 5 of the reasons; T 402/89 of 12 August 1991, point 2 of the reasons; T 73/92 of 25 March 1996, point 7 of the reasons; the latter neither published in OJ EPO). Hence, the product, when obtained by any process of preparation, is also within the scope of protection conferred by the product claim. In the present case, the product claim of the patent in suit after amendment confers absolute protection to the particular tetrakis [3- (3, 5-di-tert. buty1-4-hydroxypheny1)-propiony1-oxymethy1] methane as defined therein. Thus, that particular tetrakis [3-(3,5-di-tert.buty1-4-hydroxypheny1)-propiony1-oxymethy1] methane, obtained by any preparation process other than that defined in the process claims as granted, is also protected by the product claim as amended.

4.4 The Appellant attempted to overcome this objection in formulating the product claim as amended in the form of a product-by-process claim using the term “directly obtained”. He argued that this formulation of the claim, borrowed from Article 64 (2) EPC, restricted the protection conferred exclusively to that product which is directly obtained by the process of the claims as granted. The product claim as amended, thus, would not confer absolute product protection regardless of how the product was obtained, and did not extend the protection conferred by the claims as granted, a view which the Board does not share. In the present case the claim as amended is a claim to a product even if the product is defined in terms of a process for its preparation. Thus, despite the fact that this product is

> characterized by the process for its preparation, the claim nevertheless belongs to the category of claim directed to a physical entity, i.e. a product (cf. point 4.2 above). A product-by-process claim is interpreted according to the jurisprudence of the Boards of Appeal as a claim directed to the product per se, since the reference to a process for its preparation serves only the purpose of defining the subject-matter for which protection is sought, which is a product. Whether or not the term "directly obtained" or any other term, such as "obtained" or "obtainable", is used in a product-by-process claim, the category of that claim does not change as it is directed to a physical entity and the subject-matter of the claim, for which protection is sought, remains the product per se (see decisions T 411/89 of 20 December 1990, point 2.2 of the reasons; T 407/90 of 3 November 1997, point 2.5.3 of the reasons; neither published in OJ EPO; T 19/90, OJ EPO 1990, 476, point 4.9.2 of the reasons).Therefore, irrespective of how a product-by-process claim is worded, it is still directed to the product per se and confers absolute protection upon the product, precisely as any other claim to a product per se. That product claim, hence, confers protection upon the product regardless of the process by which it is prepared. In the present case, irrespective of the wording of the product-by-process claim of the patent in suit as amended, that claim is directed to a physical entity, i.e. the particular tetrakis [3-(3, 5 di-tert. buty1-4-hydroxypheny1)-propiony1-oxymethy1]methane, regardless of the process by which it is in fact prepared. Thus, the product-by-process claim as amended does extend the protection conferred by the process claims as granted."

121. We also take note of the following pertinent observations as were rendered by the Board of Appeal of the EPO in **Johnson Matthey PLC**[30]:-

> **"2.1** Granted claim 1 defines and protects a catalyst as such. It is an accepted principle underlying the EPC that a claim to the physical entity per se, such as a product in the form of a catalyst, confers absolute protection upon such physical entity, for all uses of such physical entity, whether known or unknown (Case Law of the boards of appeal of the European patent office, 5th edition 2006, III.B.4). Whether or not the claimed catalyst has been produced by a known or unknown process does not play any role.
>
> **2.2** Independent claim 7 of the patent in suit is directed to a process claim and defines the calcination temperature being

[30]Case Number:T 0956/04

between 200 and 600ºC. That temperature limitation was incorporated into the process claim during the examining procedure. The limitation to the calcination temperature is restrictive for that process claim but does not influence the protection conferred by independent product claim 1 as granted. The protection conferred by the two claim categories is to be considered independently. Claim 1 protects the catalyst as such, and is not restricted to how it is produced, whereas claim 7 protects a process and in addition only the catalyst directly obtained by the process (Article 64(2) EPC). Consequently, the protection of the directly obtained product of the process claim under Article 64(2) EPC does not affect the protection of an independent product claim which is also defined by "obtainable-by" features (see Caw Law, supra, II.B.6.1).

2.3 Consequently, the allowability of the product claim by "obtainable-by" features without indicating the calcination temperature according to claim 7 as granted only depends on whether or not such an amendment has a basis in the application as filed. There is a proper basis for a process for preparing such a catalyst in the application as filed without indicating the calcination temperature (claims 7 and 9 and page 6, lines 6 and 21). The board does not see any reasons, why the claimed "obtainable-by" features extend the scope of the protection of the granted product claim. Thus, the amendments made to the claims of the main request meet the requirements of Article 123, paragraphs (2) and (3), EPC.

3.2 According to the established case law, "claims for products defined in terms of processes for their preparation (known as product-by-process claims) are admissible only if the products themselves fulfil the requirements for patentability and that there is no other information available in the application which could have enabled the applicant to define the product satisfactorily by reference to its composition, structure or other testable parameters" (Case Law, supra, II.B.6.1; T 150/82, OJ EPO, 1984, 309, see point 10. and headnote II). As regards the above second requirement, in the present case, information is available in the application as filed, on how to define the catalyst by composition parameters for example by preferred amounts of cobalt, preferred cobalt metal surface area and the type of alumina (see page 5, lines 6 to 17, 24, 25, 30 and 31 as well as claims 3 to 6). None of these possibilities, however, have been introduced in claim 1 of the main request, since the appellant wishes to rely on features such as crystallite size and distribution which are not defined in the application as filed. Since there is no other information available in the application as filed for the desired limitation by reference to crystallite size and distribution, the question arises whether the products themselves as defined by

the "obtainable-by" features in claim 1 would fulfil the requirements for patentability."

122. Of equal significance are the following observations which appear in *Kirin Amgen:*

"**87.**Section 1(1)(a) of the Act says that a patent may be granted only for an invention which is new and section 2(1) says that an invention shall be taken to be new if it does not form part of the state of the art. The Act assumes that any invention will be either a product or a process (see the definition of infringement in section 60.) Claim 26 is to a product, namely a polypeptide which is the expression in a host cell of a DNA sequence in accordance with claim 1. Such a product is EPO and the question is whether it is new or the same as the EPO which was already part of the state of the art, namely the Uepowhich Miyake and others had purified from urine.

88. The practice in the United Kingdom under the Patents Act 1949 and earlier was to treat the fact that a product was made by a new process as sufficient to distinguish it from an identical product which was already part of the state of the art. This was not particularly logical, because the history of how a product was made is not an attribute which it carries around and makes it something new. It was still the same product, even if made in a different way. But the English practice had practical advantages when the extent of protection conferred by a patent was undefined (as it was until 1977) and it was assumed that a process claim could be infringed only by using that process in the United Kingdom. A product-by-process claim had the advantage of enabling the inventor of a new process to pursue not only the manufacturer who infringed his claim to the process but also, by virtue of the separate "product-by-process" claim, anyone who dealt in a product which had been made by that process. That was particularly useful in the case of the importation of a product made by someone outside the jurisdiction by a process which would have infringed the process claim if it had been made in this country.

89. The EPC, however, contains a provision which allows a patentee to rely directly on his process claim to allege infringement of a product made (whether within the jurisdiction or abroad) by that process. This is article 64(2) (given effect in United Kingdom domestic law by section 60(1)(c) of the Act):

> "If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process."

> **91.**The only case in which the EPO will accept a claim to a product defined in terms of its process of manufacture is when the product is new in the sense of being different from any existing product in the state of the art but the difference cannot be described in chemical or physical terms. As the Board said in *International Flavors* (at paragraph 8):
>
> > "This may well be the only way to define certain natural products or macromolecular materials of unidentified or complex composition which have not yet been defined structurally."

123. As would be evident from a reading of the aforesaid passages, a product-by-process was understood by the House of Lords in *Kirin Amgen* of having the advantage of enabling the inventor of a new process to prosecute not only a manufacturer who infringed its claimed process but additionally by virtue of a product-by-process claim to also proceed against one who had dealt in a product which had been made by the process. It also took note of Article 64(2) of the European Convention and principles whereof find resonance in Section 60(1)(c) of the Patent Act, 1977 prevalent in England, of a process patent extending the protective reach to products directly obtained by such a process. *Kirin Amgen* also recognized the principle adopted by the EPO of accepting a claim to a product defined in terms of its process where the product itself be new and its attributes not being capable of being described in chemical or physical terms. The House of Lords then proceeded further to observe as follows:

> "**97.** Both the judge and the Court of Appeal rejected this argument as a matter of law, and for similar reasons. In the Court of Appeal, Aldous LJ said:
>
> > "The [Technical] Board [of the EPO] accepted that it is permissible to have a claim to a product defined in terms of a process of manufacture, but state that such claims should only be granted in cases when the product cannot be satisfactorily defined by reference to its composition,

structure or other testable parameter. That is a rule of practice which is not the concern of the national courts."

98. That is, I must respectfully say, an incomplete statement of the position of the Board. The first requirement is that the product must be new and that a difference in the method of manufacturing an identical product does not make it new. It is only if the product is different but the difference cannot in practice be satisfactorily defined by reference to its composition etc that a definition by process of manufacture is allowed. The latter may be a rule of practice but the proposition that an identical product made by a new process does not count as new is in my opinion a proposition of law. It cannot be new in law but not new for the purposes of the practice of the Office.

99. Aldous L J then went on to say "it seems that the Office concluded that claim 26fell within the type of case where the product could not be satisfactorily defined by its features." That is true, but again incomplete. The important point is that the Office found that rEPO according to claim 26 was a new product because its glycosolation pattern would necessarily be different from that of uEPO. Once this finding of fact was removed, there was no basis for allowing claim 26."

124. When the issue of product-by-process claims again arose for consideration in *Hospira UK Limited*, the Court observed:

"**126.** One of the key problems which a system of patents for inventions has to handle is how to legislate for future inventive (non-obvious) developments. By definition they are often hard to foresee. One way this is done is to give inventors more or less complete freedom in the drafting of their patent applications. They can define the invention in a claim in any way and using any language they like so long as the definition is clear to a person skilled in the art and the invention satisfies various other criteria.

127. Most inventions are either products or processes and it has proved possible for the law to define acts of infringement by reference to these different kinds of inventions. Section 60 of the Patents Act 1977 does just this. It is based on the Community Patent Convention (CPC) rather than the EPC. The way s60(1) is drafted one might assume that an invention must be either a product or a process. There is no such rule. By and large the system works but there can be difficulties. A well known example is a new pharmaceutical use of an old drug which gives rise to Swiss style claims. Infringement of these claims is often argued only under s60(2) (infringement by supplying means

essential) which avoids the problem of deciding whether it is a product or a process.

128. Another kind of claim which straddles the boundary between products and processes is a product by process claim. As a matter of language there are two kinds: (1) a product "obtained by" a process, and (2) a product "obtainable by" a process. At least at first sight they are different.

129. At first sight the scope of a claim to a product "obtained by" a process would be only to products which had actually been made by the process. There might be problems of proof in an infringement case or for novelty but conceptually there is no difficulty. If no products had ever been made that way in the past, then the claim would be novel. The fact that such products are physically entirely identical to products made in the past would not alter the fact that no product made by that process had been made available to the public before. They would only be infringed by products actually made by the relevant process. This was the view taken of product by process claims in the Court of Appeal in ***Kirin Amgen*** ([2002] EWCA Civ 1096, [2003] RPC3)

134. The view taken by the EPO in the 1980s (see e.g. ***IFF / Claim Categories*** T150/82and later cases T248/85 and T219/83) was firmly against the idea that an old thing could be patented using product by process language. The EPO held that defining a product by the process by which it was made could not confer novelty on a product which was known *per se*. The product itself had to be novel. In effect in these cases the EPO was deciding to treat "obtained by" claims and "obtainable by" claims in the same way, at least for its purposes, i.e. for validity. Regardless of the claim wording, all claims were treated as if they meant "obtainable by". If the process conferred a particular characteristic on the product then one could take that characteristic into account. But if not, then the process feature made no difference and the product was not different from the prior art. The product would lack novelty.

135. The EPO's approach to overt product by process claims today is settled. They will be permitted (and only permitted) if there is no other way of defining the product open to the patentee. This is a decision based on policy. Such claims present clarity problems and are best avoided but if there is no alternative way of defining the characteristic in question, then they will be permitted.

136. But despite their apparently esoteric nature (even by the standards of patents) product by process language is actually quite common and hardly remarked upon. Claim 1 of628 as granted is a product claim which uses process language in an

unexceptional way. The opening words are "*A formulation comprising a lyophilised mixture of...*".This is a claim to a product defined by reference to the process by which it has been made. Claims drafted this way are granted routinely and rarely raise any issue. No one calls these claims product by process claims and the EPO does not apply its case law to this language. That is why I referred to "overt" product by process claims in the previous paragraph.

139. In ***Kirin-Amgen*** the Court of Appeal had held that the product by process claim(claim 26) was novel because of the novel process feature. The Court of Appeal had refused to follow the EPO's practice about permitting such claims only in certain circumstances because that was a rule of practice of no concern to national courts. Lord Hoffmann (with whom the other lords agreed) did not agree with the Court of Appeal's reasoning (paragraphs 98-101). He held that a difference in the method of manufacturing did not make a product new and that was so as a matter of law. On that basis the claim could only be novel if the process definition gave the product a new characteristic of some kind. On the finding of fact in ***Kirin-Amgen***, therefore claim 26 lacked novelty since the process did not necessarily do so. The decision of the Court of Appeal was wrong. The UK should follow the approach of the EPO.

140. Therefore the ratio of the decision in ***Kirin-Amgen*** is that an identical product made by a new process does not count as new. In that respect the UK now follows the EPO. Lord Hoffmann did not agree with the Court of Appeal's decision but the focus of his disagreement was not about the EPO's rule of practice, the issue was that there was a point of law underpinning that practice. Lord Hoffmann was concerned to align the UK law of novelty with the law applied in the EPO. Beyond a need for a claim to be novel, he was not commenting on whether the EPO's practice was sound or not and did not comment on the Court of Appeal's refusal to follow it as a rule of practice only, subject to applying the correct law of novelty."

125. The Court also emphasised the imperatives of aligning the view liable to be taken by authorities in the UK with the principles followed by the EPO. It ultimately culled out the following principles:-

"**147.** I derive the following principles from this consideration of the EPO and UK authorities:

i) A new process which produces a product identical to an old product cannot confer novelty on that product. To be novel a product obtained or obtainable by a process has to

> have some novel attribute conferred on it by the process as compared to the known product.
>
> ii) This rule is a rule of the law of novelty. It is not a principle of claim construction. Although in effect the rule treats "obtained by" language as "obtainable by" language, nevertheless as a matter of claim construction a claim to a product "obtained by" a process means what it says. That will be the relevant scope of the claim as far as infringement and sufficiency are concerned.
>
> iii) Although normally a patent is drafted by the inventor "in words of his own choosing", the EPO will not permit overt product by process language unless there is no other alternative available. By no other alternative, they mean no other way of defining a particular characteristic of the product in question."

126. In our considered opinion, once product-by-process claims are conceptually accepted and acknowledged, it would be wholly incorrect to hold that products must necessarily and invariably be described by their composition and structure. That would go against the very grain of product-by-process claims as understood in patent jurisprudence. As has been recognised by jurisdictions across the globe, a product-by-process claim is permitted where it is found that it would be difficult to define the product with reference to its structural features. Such claims are allowed where it is not possible to satisfactorily or with sufficient clarity explain the characteristics of a novel invention on the basis of its composition or structural parameters. Patent Registries globally acknowledge and accept the possibility of structurally indefinable products. In fact, it is the acceptance of this facet of such claims which constitutes the point of origin of product-by-process claims. Such claims are permitted in situations where although the product is patentable, it defies definition and explanation in terms ordinarily accepted. However, and undisputedly, even the decisions and the material on which the learned Judge ostensibly rests the impugned

decision do not recognise product-by-process claims as not relating to a product at all. What would be the position of such claims in cases of alleged infringement is an issue which is separate and shall be dealt with in the latter parts of this decision.

127. One principle which finds resonance across jurisdictions and stands embodied even in the guidelines framed by the IPO, EPO and the USPTO is that a product-by-process claim would be accepted and accorded statutory protection, only if the product itself be novel. Irrespective of the language in which such a claim may be couched, it is necessary that such a patent application speak of a novel product. It is this foundational precept on which product-by-process claims are tested. This is evident when the guidelines urge us to bear in mind that novelty of a process does not necessarily mean that the product itself represents an invention. The guidelines as well as the judgments rendered in the context of product-by-process claims speak in unison when they state that for assessing novelty one must disregard the process terms and discern whether the product possesses novelty. We are reminded that a product is not rendered novel merely by virtue of the fact that it is produced by a new process. This since if novelty is claimed only in respect of a process, it would be treated and granted as a process patent.

128. It is thus manifest that for a patent application founded on a product-by- process claim being granted, it is imperative that it relate to an inventive and novel product notwithstanding the invention having been explained in process terms. The aforesaid discussion leads us to the irresistible conclusion that even in the case of product-by-process claims, it is the novelty of the product which must be established shorn of the process terms that may accompany such a claim. The primary

focus even in such claims is thus directed towards the product as opposed to the process of manufacture. In fact, even the respondents before us did not dispute that the aspect of novelty of the product would be paramount for the purposes of considering patentability notwithstanding it being a product-by-process claim. The respondents essentially commended us to accept and acknowledge a principled distinction that is liable to be drawn between the test of novelty as applicable at the stage of grant of a patent and the manner in which such claims should be construed in the course of infringement analysis.

129. At the outset we note that the learned Judge appears to have clearly erred in holding that a claim to a product must necessarily and inviolably be explained by its structure. The acceptance of such a test would undoubtedly inhibit and constrict the structuring and formulation of claims relating to inventions which defy explanation in terms ordinarily recognised. The test as formulated also fails to bear in mind applications that may relate to novel chemical formulations and drugs in particular and the fact that product-by-process claims is the methodology often adopted in respect of such products. This more so where the composition or the constituents of the product cannot be explained in explicit terms except by reference to a process of manufacture. The acceptance of such a precept not only fails to bear in consideration the contingency of the patent application being filed at a time when the compound may not have been ascribed a name duly recognised or may not be ascribable but also stifles the filing of applications for grant in such contingencies. The test as formulated by the learned Judge thus clearly impedes and inhibits the filing of patent applications in such situations.

130. The learned Judge also appears to have veered around to the view that notwithstanding the product being novel, if the claim be expressed in process terms, the patentee's right must be confined to the process alone. This appears to proceed apparently on the basis of what was observed by the majority in *Abbott Laboratories*. This we observe since, although the learned Judge has referred to *Kirin Amgen*, *Hospira UK Limited* and *Abbott Laboratories*, there is neither an expressed affirmation of those decisions nor do we have the benefit of the learned Judge having articulated or identified the key takeaways from those decisions.The aforesaid line of reasoning in any event appears to be untenable and illogical for reasons which are spelt out hereinafter.

131. Let us then proceed to consider whether process terms when employed in a claim are limiting and if the principle of novelty is to be understood as taking on a different complexion and hue dependent upon whether the same is raised while dealing with patentability or when it arises in the context of infringement. Before the learned Judge reliance appears to have been placed upon the decision of the House of Lords in *Kirin Amgen* and the decision of the High Court of England and Wales in *Hospira UK Limited*. According to the respondents the interpretation accorded to product-by-process claims in the aforenoted two decisions are liable to be read as supportive of their contention that the principle of novelty which may be applicable and relevant at the stage of grant would be wholly irrelevant when tested in an infringement action.

132. As a preface to the discussion which ensues, it must be stated that the language of Section 48 is suggestive of the statute accepting patentability residing or being recognised to exist in either a product or a process. We have already held that a product-by-process claim though

employing process terms is fundamentally concerned with an inventive product and the reference to process being only to aid in explaining the novel attributes of a new product unknown in the prior art. We are thus of the firm opinion that it would be unjust and incorrect to cut down or trim a claim pertaining to a product per se to merely a process. That would clearly be doing violence to well established tenets of claim construction. According such an interpretation firstly proceeds on the premise that notwithstanding the product being novel, it must be presumed that the patentee sought and claimed protection only over the process and thus the same acting as a limitation. More fundamentally, that interpretation commands us to ignore the undisputed fact that such a claim may in fact have been recognised at the stage of grant as a novel product. We propose to elaborate upon these aspects hereinafter and set out our reasons why we have found ourselves unable to countenance or accept the line of reasoning as suggested by the respondents.

133. As was noticed by us hereinabove, the statute confers a right upon the patentee to restrain the making or using of a product or a process. However, and as was observed in *Hospira UK Limited*, the dichotomy between a product and a process is not liable to be viewed as operating in a water tight compartment. The appellants contend that a product-by-process claim though incorporating process terms essentially remains one pertaining to a product. This is so urged in light of the compulsions which according to the appellants operate and constrict the applicant to describe a complex product with the aid of the manner in which it is actually produced or manufactured. We have already found that a product-by-process claim is essentially a hybrid

which straddles the fence that is ordinarily understood to exist between a product and a process.

134. Taking up the decision in *Kirin Amgen* first, we note that the subject patent pertained to 'erythropoietin', which was a hormone found in the human kidney. *Kirin Amgen* found that erythropoietin was a product which was thus naturally occurring. While dealing with the principles which must weigh in the construction of claims, *Kirin Amgen* firstly took note of the common principles of guidance pertaining to claim construction in the European Protocol and the legal position in England. This is evident from the following observations as appearing in para 47:

> "**47.**The Protocol, as I have said, is a Protocol for the construction of article 69 and does not expressly lay down any principle for the construction of claims. It does say what principle should not be followed, namely the old English literalism, but otherwise it says only that one should not go outside the claims. It does however say that the object is to combine a fair protection for the patentee with a reasonable degree of certainty for third parties. How is this to be achieved? The claims must be construed in a way which attempts, so far as is possible in an imperfect world, not to disappoint the reasonable expectations of either side. What principle of interpretation would give fair protection to the patentee? Surely, a principle which would give him the full extent of the monopoly which the person skilled in the art would think he was intending to claim. And what principle would provide a reasonable degree of protection for third parties? Surely again, a principle which would not give the patentee more than the full extent of the monopoly which the person skilled in the art would think that he was intending to claim. Indeed, any other principle would also be unfair to the patentee, because it would unreasonably expose the patent to claims of invalidity on grounds of anticipation or insufficiency."

135. As is manifest from the aforesaid passage, *Kirin Amgen* acknowledged the jettisoning of the archaic test of *"English literalism"* and spoke of how a claim was liable to be understood by the notional

addressee. Para 47 thus attempted to draw a just balance between the expectations of the patentee while at the same time avoiding the specter of "over-protectionism". This aspect pertaining to construction of claims was again reiterated in para 70 and 80 which read thus:

> "**70.**I agree with the Court of Appeal that the invention should normally be taken as having been claimed at the same level of generality as that at which it is defined in the claims. It would be unusual for the person skilled in the art to understand a specification to be claiming an invention at a higher level of generality than that chosen by the patentee. That means that once the judge had construed the claims as he did, he had answered the question of infringement. It could only cause confusion to try to answer the Protocol questions as well.
>
> **xxxx xxxx xxxx**
>
> **80.**I do not dispute that a claim may, upon its proper construction, cover products or processes which involve the use of technology unknown at the time the claim was drafted. The question is whether the person skilled in the art would understand the description in a way which was sufficiently general to include the new technology. There is no difficulty in principle about construing general terms to include embodiments which were unknown at the time the document was written. One frequently does that in construing legislation, for example, by construing "carriage" in a19th century statute to include a motor car. In such cases it is particularly important notto be too literal. It may be clear from the language, context and background that the patentee intended to refer in general terms to, for example, every way of achieving a certain result, even though he has used language which is in some respects inappropriate in relation to a new way of achieving that result: compare *Regina (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687. In the present case, however, I agree with the Court of Appeal (and with the judge, before he came to apply the Protocol questions) that the man skilled in the art would not have understood the claim as sufficiently general to include gene activation. He would have understood it to be limited to the expression of an exogenous DNA sequence which coded for EPO."

136. Proceeding then to the issue of novelty in the context of product-by-process claims, the House of Lords in *Kirin Amgen* appears to have moved closer to the position accepted in the EPO when they held that a

product-by-process claim would enable the inventor to pursue an infringement action not just with reference to the process but also the product embodied in such a claim. This is evident from the observations appearing in paragraphs 88 & 89 which have been extracted hereinabove. Lord Hoffman in his speech further referred to the European position as evident from the principles enunciated by the Technical Board of Appeal in *International Flavors*. Of crucial significance, however, are the observations appearing in paragraphs 98 & 99. The House of Lords categorically held that a product-by-process claim would be accepted only if the product was different and its distinctive characteristics could not be satisfactorily defined with reference to its composition except by a definition pertaining to the process of manufacture. However, it was held that while the aforesaid precept may be a rule of practice, it must in law be accepted that an identical product merely made by a new process would not be compliant with the rule of novelty. It was on this basis the Court in *Kirin Amgen*, proceeded to hold that once it was found that the rEPO could not be visualised as a new product, the very basis of claim 26 would disappear. Before closing the discussion on *Kirin Amgen*, it may only be noted that the position of claims being interpreted bearing in mind principles of *purposive construction* is no longer in doubt in light of the decision of the UK Supreme Court in **Actavis UK Ltd. and others Vs. Eli Lilly & Co.**[31]

137. *Hospira UK Limited* was concerned with Trastuzumab which was a product already known and the claim in *Hospira UK Limited* was itself worded in "obtained by" terms. The Court of Appeal firstly held

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that notwithstanding the manner in which Section 60of the Patents Act 1977 is drafted [a provision which is *pari materia* to Section 48 of our Act] while it may be easy to assume that an invention must be either a product or a process, there is no such rule. The Court of Appeal specifically alluded to the difficulties which would arise where the product related to a new pharmaceutical use. They noticed claims falling in the genre of product-by-process being construed either as a product "obtained by" a process or one "obtainable by" a process. The Court in *Hospira UK Limited* proceeded to observe that while such claims may raise difficulties of proof in cases of infringement or while deciding the question of novelty, the same would not be insurmountable since if no product identical to the one claimed had been made in the past, the claim must be recognized as being novel. *Hospira UK Limited* as was noticed hereinbefore was principally dealing with an *"obtained by"* claim. It also recognised *Kirin Amgen* as being an authority for the proposition that infringement of "obtained by" claims would be answered in the affirmative only if it were found that the infringing product had actually been made *"by the relevant process"*.

138. The Court further observed that when claims utilize the expression *"obtainable by"* they essentially intend to cover a product which was never earlier made by the defined process but could have been. Noticing the decision in *Johnson Matthey*, *Hospira UK Limited* in para 132 acknowledged the intent of the patentee as being to claim a product irrespective of how it was made. This observation was made in the light of Claim 1 in *Johnson Matthey* having adopted the *"obtainable by"* language. It was, however, accepted and acknowledged that a product already existing in the prior art could not be patented by mere usage of product-by-process language. The Court

of Appeal in *Hospira UK Limited* also acknowledged the settled and unquestioned practice of the EPO as is evident from paras 134 and 135. However, on facts, they ultimately found that Claim 1 appeared to have been drafted as claiming a product defined with reference to the process by which it was made. They proceeded to notice the fundamental precept as enunciated in *Kirin Amgen* as being that an identical product would not count as new merely on account of adoption of a new process for its manufacture. This, their Lordships held, would be the principle which has come to be adopted by Courts in England also. The aforesaid also flows from the principles which were culled out and find place in para 147.

139. What the respondents, however, contend is that *Hospira UK Limited* must be recognised as an authority for the proposition that the principles of claim construction which may apply while answering a question of patentability would not be relevant in actions for infringement. That would appear to be not only factually incorrect but also a complete misreading of those two decisions. In our opinion, the said judgments can by no stretch of reasoning be recognised to be an authority for the principle as propounded by the respondents. It becomes pertinent to note at the cost of repetition that *Hospira UK Limited* was concerned with a claim which had employed *"obtained by"* language and which in that sense is identical to what occurs in Section 48(b) of our Act and which extends to products obtained directly by a process. This in addition to the undisputed position of *Hospira UK Limited* being concerned with a product known in the prior art. In our considered opinion, the respondents clearly misconstrue the dictum of *Hospira UK Limited* while seeking to pick out a few strands from para 147 (ii) ignoring the well settled precept that observations

appearing in a judgment should not be read in isolation but as part of larger canvas which stands sketched. In any event, as is evident from a close reading of that passage, *Hospira UK Limited* merely holds that a claim to a product *"obtained by"* a process would confine the scope of the claim so far as infringement and sufficiency are concerned. In doing so, *Hospira UK Limited* merely answered the issue which stood raised based on settled principles of claim construction and purposive interpretation.

140. The respondents also appear to have completely misunderstood the dictum of *Hospira UK Limited* when it was suggested that it had deprecated the practise of product-by-process claims or that it had propagated the principle of process terms being limiting. The respondents omit from consideration the following observations of seminal import which find place in paras 157 to 159 of that decision:-

> "**157.** I confess that trying to apply the EPO's stated approach is not easy but my tentative conclusion is that Genentech's submission is wrong. The EPO's practice is not that product by process claims are a sort of last resort when all else fails in the sense that every other claim is invalid. That sort of approach would be unprincipled. On that basis they would be available in all cases. Since the EPO's practice runs counter to the idea that a patentee is entitled to use words of his own choosing in describing his invention, it must be based on some principle. The principle underlying the EPO's practice is shown by the Johnson Matthey case. It is a principle of clarity (Art 84 EPC, s14 of the 1977 Act) and amounts to a trade off between clarity and fairness, tolerating an increased lack of clarity in that limited class of cases. If a patentee can identify a characteristic or parameter disclosed in the patent for which no other definition is available in the specification other than an "obtainable by" process definition, then a product by process claim may be allowed as a way of claiming that attribute. It is impossible to apply that approach properly without knowing what characteristic the process feature is to be used to define. That would be best stated in the claim expressly but it may be clear from the specification.

> **158**. Proposed claim 1 of 628 does not expressly state which characteristic is referred to. The skilled reader could draw up a list of characteristics but they would not know which one was intended either from the claim or from the specification as a whole. The only realistic conclusion is that every conceivable characteristic is caught by the definition. Maybe in some cases that would not cause a difficulty but here to say that every feature is relevant leaves the reader with the impossible task of having to createfor themselves a list of relevant attributes. The fact the skilled reader would include molar ratio on the list does not help.
>
> **159**. Not without some hesitation, it seems to me that a principled application of the EPO'sstated approach must lead to refusal of this amendment. My hesitation derives from the fact that I suspect in practice the EPO has permitted product by process claims in the past even when they do not expressly recite the attribute(s) to which the language applies. However since the reader of claim 1 of 628 cannot identify all the attributes to which the language applies, I do not see how I can permit a claim in that form. The fact the skilled reader of the 628 patent can identify one attribute is not sufficient since the reader would understand that there would in all likelihood be further attributes to which the product by process language alsoapplies but that would be an indefinite class of attributes. Accordingly I will not permit the amendments to allow proposed claim 1 of 628 nor proposed claims 1 and 3 of 119. It makes no difference whether these claims use the words "consisting of" rather than "comprising".

141. *Hospira UK Limited* eloquently explains the *raison de' etre* for the acceptance of product-by-process claims as being founded on the needed imperative of striking a balance between *"clarity and fairness"* and according a limited leeway in that *"limited class of cases"* where the patentee is unable to identify a characteristic or parameter disclosed in the patent except by way of an *"obtainable by"* process definition. It thus formulates the tests to be borne in mind while evaluating such a claim to be whether a characteristic or attribute is discernible from claims structured in product-by-process terms. Viewed in that light, it is manifest that the decision propounds a reasoned, just and balanced threshold for examination of product-by-process claims.

142. Turning back to our statute, it becomes pertinent to observe that Section 48(b) on its plain language is concerned with a process patent per se. It is with the aforesaid objective that the Act proceeds to create a statutory bar and prevents third parties from either using the patented process or employing the same for the purposes of manufacture of a product which could be said to have been directly obtained from that process. Section 48(b), however, does not adopt the *"obtainable by"* language while referring to a process claim. In our opinion, a process claim and the extent of protection that can be claimed in respect thereof would have to draw colour and content from Section 48(b) and which embodies the phrase *"obtained directly by that process"*. We would thus draw and acknowledge the existence of a distinction between *"obtained by"* and *"obtainable by"* language embodied in the claim. The words *"obtainable by"* would appear to convey a descriptive process by which the claimed product could be manufactured or produced. However, that process in itself need not and invariably be the inventive element of the patent. This since we are considering the usage of the expression *"obtainable by"* in the context of a product-by-process claim. The expression *"obtained by"* on the other hand would be intended to convey a direct linkage between the product and the process. However in the context of our statute, the latter would in most situations be concerned with a process claim referable to Section 48(b) and ultimately liable to be construed accordingly be it for patentability or infringement analysis. Consequently, an *"obtained by"* claim tested whether on the anvil of Section 48(b) or the canons of claim construction would lead us to the same conclusion, namely, the patentee having intended to restrict the scope of the claim to the recited

process. This would also follow when examined from the eye of the notional audience.

143. Ultimately, and as we have held hereinbefore, a product-by-process claim would have to meet the test of pertaining to a novel and inventive product as opposed to a mere process. It will thus be wholly incorrect to abridge or truncate a product-by-process claim to fall within the ambit of Section 48(b). In our considered opinion as long as the product-by-process claim pertains to a product which is novel and inventive and unknown in the prior art it would remain a product which would fall within the ambit of Section of 48(a). Ultimately, courts when faced with such claims would have to discern from the language of the claim and the specifications whether the claim pertains to an inventive product or merely a novel process. The difficulty in discerning the scope of such claims would not constitute a valid basis to deprive a true invention of the protective cover which the Act confers. In any event, it would be wholly incorrect and unjust to postulate a rule that product-by-process claims must be inevitably curtailed by process terms.

I. GRANT AND INFRINGEMENT – DISSIMILAR STANDARDS?

144. As would be evident from the preceding parts of this decision, the fact that product-by-process is a well-accepted and known concept in the drafting of claims is clearly incontestable. That the practice is conventional and established was also not questioned before us. The solitary bone of contention was the extent of protection that could be asserted on the basis of such claims in the course of infringement analysis. The submissions advanced on behalf of the respondents essentially require us to hold that while an inventive element of a

product in a product-by-process claim may be relevant for examining patentability, the same is rendered inconsequential when it comes to trying an infringement action. According to the respondents, in case of infringement, protection must be recognised to extend only to the process. They would assert that the patentee must be held bound to the language of the claim. According to the respondent, the adoption of process terms should be read as protection claimed only in respect of the process. It was argued that *Abbot* had correctly enunciated the tests that must be applied while trying an infringement action.

145. Reverting then to our reservations in accepting the line suggested for our consideration by the respondents and pertaining to process terms being limiting in infringement analysis, we note that at least the provisions of our Act do not appear to sanction, create or construct a distinction between factors relevant for grant and those which would be pertinent to adjudge an infringement allegation. The primary concern of the Act is an invention as is evident from Section 2(1)(j) of the Act and which may relate not just to a new product but even a process both of which may involve an inventive step. We fail to discern any logic in recognizing distinct tests of novelty being applicable at the stage of patentability and those that may be relevant for deciding a question of infringement. It is pertinent to observe that both at the stage of grant as well as while considering an allegation of infringement the terms and the language of the claim remain unaltered. Claims and specifications do not change hues but remains static. We thus principally find ourselves unable to countenance the submission that separate or distinct tests of novelty should apply between the grant of a patent and the examination of an allegation of infringement. As long as a product-by-process claim pertains to a product, which is novel and has no parallel

in the prior art, the mere fact that the patentee chooses to describe the invention more exhaustively by reference to process terms, and in light of the difficulties of expression alluded to above, the tests should in our opinion remain unchanged. Whether the product-by-process claim does not relate to an inventive product and is confined to a novel process, would essentially turn upon the facts of each case. Only where the claim is discerned and found to be confined to a novel process would we be justified in recognising the claim as falling squarely within the ambit of Section 48(b) of the Act.

146. We further find that our Act in terms of Section 107, enables a defendant to adopt all or any of the grounds relating to revocation as encapsulated in Section 64 as a defence in a suit for infringement. This enables a defendant while contesting an allegation of infringement asserting that the patent was invalidly granted since it was known in the prior art, was granted to a person not entitled or that it does not represent an invention. The grounds on which revocation may be claimed are those which question the grant of the patent itself. It is these very grounds which are available to be urged in an infringement action. Section 64 further fortifies the aforesaid position by using the expression *"or on a counter claim in a suit for infringement of the patent..."*. We thus find ourselves unable to find a logical justification to hold that a ground for revocation which is otherwise available and which reaches out to the very grant of the patent should be denied in the course of infringement analysis.

147. We note that in the United States, the line of reasoning that we have chosen to adopt was the position in law accepted without equivocation and stood so enunciated in *Scripps*. This settled position

stood duly recognized by *Scripps* as would be evident from the following passage:

> "Scripps charges that Genentech's recombinantly-produced Factor VIII:C infringes the product-by-process claims, either literally or by application of the doctrine of equivalents. The district court remarked that the product-by-process claims would not be infringed unless the same process were practiced. Scripps correctly points out that this statement appears to diverge from our precedent, recognizing that this precedent arose in the context of patent prosecution, not patent infringement. E.g., In re Thorpe, 777 F.2d 695 , 227 USPQ 964 (Fed.Cir.1985) (holding that prior art pertinent only to product is proper ground for rejecting product-by-process claims); In re Brown, 459 F.2d 531 , 535, 173 USPQ 685 , 688 (CCPA 1972) (in product-by-process claims the patentability of the product must be established independent of the process); In re Bridgeford, 357 F.2d 679 , 682 n. 5, 149 USPQ 55 , 58 n. 5 (CCPA 1966) (recognizing that some courts in infringement litigation have construed product-by-process claims as limited to the particular process, but holding that patentability is determined independent of the process). In determining patentability, we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims. Thus, these claims are subject to an infringement analysis similar to that described in Part V,ante. Infringement of the product-by-process claims may be considered at trial."

148. The Court in *Scripps* referred to a host of precedents which had enunciated the principles which must govern the interpretation of product-by-process claims and ordained that the patentability of the product must be established independent of the process. It went on to significantly observe that claims must be construed identically for the purposes of validity and infringement. It is this position which was sought to be departed from by the majority ruling in *Abbott Laboratories*. The principles spelt-out in *Scripps* again came to be reiterated in **SmithKline Beecham Corporation vs. Apotex**

Corporation[32]. It becomes pertinent to observe that the judgment in *SmithKline* came to be rendered just after *Atlantic Thermoplastics*. While dealing with product-by-process claims, we find the following instructive passages in *SmithKline*:

> "Regardless of how broadly or narrowly one construes a product-by-process claim, it is clear that such claims are always to a product, not a process. It has long been established that one cannot avoid anticipation by an earlier product disclosure by claiming the same product more narrowly, that is, by claiming the product as produced by a particular process. This was the exact issue in *In re Thorpe*. There, the patent concerned a composition that was used in carbonless copy paper systems.777 F.2d at 696. The composition was known in the prior art, but was previously made using zinc dibenzoate. In a product-by-process claim, Thorpe claimed the same composition made by a process that used zinc oxide and benzoic acid, rather than zinc dibenzoate. The court upheld the PTO's rejection of the claim. *Id*. at 698. It held hat "if the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Id. at 697. *In re Thorpe* has never been overruled and has been followed for many years by the PTO. The current MPEP states:
>
> > *[Even] though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.*
>
> MPEP $ 2113 (8th ed., Rev. 2, May 2004) (quoting In re Thorpe, 777 F.2d at 698).
>
> > At the time of *In re Thorpe*, the rule as articulated was hardly new. Long before *In re Thorpe*, our predecessor court, the Court of Customs and Patent Appeals, consistently held that product-by-process claims could not validly claim products already known in the art. See *In re Fessmann* 489 F.2d 742, 744-45 (C.C.P.A, 1975); *In re Johnson*, 55 C.C.P.A. 1463, 394 F.2d 591, 594-95 (1968); *In re Stephens*, 52 C.C.P.A. 1409, 345 F.2d 1020, 1023

[32] 439 F.3d 1312 (Fed. Cir. 2006)

(1965) ("We think it well settled that the presence of process limitations in product claims, which product does not otherwise patentably distinguish over the prior art, cannot impart patentability to that product."); *In re Dilnot* 49 C.C.P.A. 1015, 300 F.2d 945, 950 (1962) ("The addition of a method step in a product claim, which product is not patentably distinguishable from the prior art, cannot impart patentability to the old product."); *In re Moeller*; 28 C.C.P.A. 932, 117 F.2d 565, 567 (1941) ("T]he article itself must be inventive and patentably distinct from such articles disclosed in the prior art."); *In re Ewert*, 22 C.C.P.A. 1262, 77 F.2d 498, 499 (1935); *In re Brawn*, 22 C.C.P.A. 1239, 77 F.2d 362, 363 (1935); *In re Harvey*, 21 C.C.P.A. 1155, 71 F.2d 200, 201 (1934).

This rule is also supported by earlier Supreme Court cases. For example, in *Cochrane v. BadischeAnilin& Soda Fabrik*, 111 U.S. 298, 4 S.Ct. 455, 28 L.Ed.433 (1884) *("BASF"),* natural alizarine was already known in the art. *Id*. at 311, 4 S.Ct. 455. However, BASF obtained a patent covering artificial alizarine, as produced by a bromine reaction process. Id. at 296, 111 U.S. 293. The accused infringer, Cochrane, then sold artificial alizarine made by a different, sulfurie acid reaction process. *Id*. at 309, 4 S.Ct.455. The Court reasoned that if the BASF patent were construed to cover the product itself, it would be invalid because the product was old. *Id*, at 311-12, 4 S.Ct.455. The Court stated that "[w]hile a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time….." *Id.* At 311, 4 S.Ct. 455. As the *Atlantic Thermoplastics* panel recognized, the *BASF* court thus held that "a patent applicant could not obtain exclusive rights to a product in the prior art by adding a process limitation to the product claim."*Atlantic Thermoplastics*, 970 F.2d at 841 (citing *BASF*, 111 U.S. at 311, 4 S.Ct. 455); *see also Tri-Wall Containers, Inc. v. United States*, 187 Ct.Cl. 326, 408 F.2d 748, 750-51 (1969), *cert. denied*, 396 U.S. 828, 90 S.Ct. 78, 24 L.Ed.2d 79 (1969) (following *BASF*, and stating that "the addition of a method step in a product claim, which product is not patent-ably distinguishable from the prior art, cannot impart patentability to the old product"). This understanding of BASF has been recognized by leading commentators. See, e.g., 3 *Chisum on Patents* § 8.05[3] (2003 ed.) (citing *BASF* for the proposition that "[e]ven through a product may be claimed in terms of the process of making it, the product still must be new in structural terms in order to meet the novelty requirement."). Other Supreme Court cases have reached the same conclusion. See *Gen. Elec. Co. v. Wabash Appliance Corp*., 304 U.S, 364, 373, 58 S.Ct. 899, 82 L.Ed. 1402 (1988)

> ("Although in some instances a claim may validly describe a new product with some reference to the method of production, a patentee who does not distinguish his product from what is old except by reference, express or constructive, to the process by which he produced it, cannot secure a monopoly on the product by whatever means produced."); *Wood- Paper Patent*. 23 Wall. 566, 90 U.S. 566, 596, 23, L.Ed. 31 (1874)."

149. The majority opinion in *Abbott Laboratories* thus for the first time appears to have taken the position that notwithstanding the overriding imperatives compelling an inventor to define its product with the use of process steps, since it chose to do so in that manner the same must govern the bounds of the patent. It held that it would be unsound to hold that process limitations should not apply where the structure of a claimed product is unknown and where it can be defined only with reference to the process. That the majority opinion in *Abbott Laboratories* constitutes a stark and significant departure from the principles governing a product-by-process claim as was consistently understood till then is evident from a reading of the dissenting opinions which were rendered. Newman, J. while penning the minority opinion at the outset notes that the majority has essentially overruled a "century of precedent" to hold that a new product though difficult to describe except with reference to its process terms and which otherwise is undisputedly new and unobvious cannot be accorded protection if its claim refers to the process by which it is made.

150. The dissent observes that the aspect of patentability of the product had always been recognised to be the same be it validity or infringement. It also speaks of the experience of patentee products whose structure at the time of filing of the patent application may not be fully known. According to Newman, J., the well accepted rule of necessity had been completely overturned and disregarded by the

judges who constituted the majority. Newman, J. observed that the majority opinion essentially accepts the proposition that the aspect of a product being new and unknown is wholly irrelevant and thus significantly impacting the class of inventions where the applicant may be constrained to describe the invention with reference to the process by which it is made.

151. The minority opinion in *Abbott Laboratories* also took note of the long established precedent of permitting inclusion of process terms in a product claim in order to aid in identifying the product itself. It referred to the origin of product-by-process claims being recognised and having been accorded a judicial imprimatur as far back as in 1891 in *Ex Parte Painter.*Newman, J. also took note of the consistent position adopted by the erstwhile **Court of Customs and Patent Appeals**[33]which had recognised the use of process terms solely as an aid in describing new products. It also took note of the undisputed fact that such claims would be accepted only if they pertained to a novel and unobvious product. It also notices a decision rendered by the CCPA in 1972 in **In re Brown**[34] which had held that product-by-process claims are directed towards the product notwithstanding the claim referring to process limitations. It also relied upon **In re Hughes**[35] and which had held that while a product-by-process claim may include process limitations, it is the product which would be covered and not the recited process steps. Newman, J. then in a detailed opinion also recorded pertinent reasons of why various precedents including that of BASF appeared to have been misconstrued by the majority. This is evident from the following extracts of the dissenting opinion:-

[33]CCPA
[34]459 F.2d 531 (CCPA 1972)
[35]496 F.2d 1216(CCPA 1974)

"The en banc opinion relies primarily on Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293 (1884) ("BASF"), even though my colleagues acknowledge that the product in that case was the well-known dye alizarine. The patent before the Court was a reissue patent that claimed artificial alizarine in the following way:

> Artificial alizarine, produced by either of the methods herein described, or by any other method which will produce a like result.
>
> The Court held that since alizarine was a known product, the claim was limited to the patentee's two processes, stating:
>
> It was an old article. While a new process for producing it was patentable, the product itself could not be patented, even though it was a product made artificially for the first time, in contradistinction from being eliminated from the madder root. Calling it artificial alizarine did not make it a new composition of matter, and patentable as such, by reason of its having been prepared, artificially, for the first time, from anthracite, if it was set forth as alizarine, a well-known substance. Wood Paper Patent, 23 Wall.560, 593 [(1874)]. There was therefore no foundation for reissue No.4,321, for the product, because, on the description given, no patent for the product could have been taken out originally.

111 U.S. at 311-12. The Court accordingly limited the claim to the two processes described in the patent, and in the portion of BASF quoted by my colleagues, the Court discussed the proofs needed to show infringement:

> [U]nless it is shown that the process of [the specification] was followed to produce the defendants' article, or unless it is shown that the article could not be produced by any other process, the defendants' article cannot be identified as the product of the process of [the specification]. Nothing of the kind is shown.

Id. at 310. The Court did not state, or imply, despite my colleagues' contrary theory, that a claim to a new and complex product that is of necessity defined and distinguished by the process by which it was made, can never be infringed unless that specific process is practiced. There was no issue in BASF of a product that could not be defined without reference to how it was made. The BASF Court, providing guidance, remarked on the importance of independent description of a patented product, in the following sentence cited by my colleagues:

> Every patent for a product or composition of matter must identify if so that it can be recognized aside from the description of the process for making it, or else nothing can be held to infringe the patent which is not made by that process.

Id. at 310. This statement is indeed the general rule, as stated by the Patent Commissioner several years later in Ex parte Painter. However, BASF did not present the situation for which the expedient of necessity was created, for as the Court stated, the invention was "a process for preparing alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine, to be prepared, however, by the new process, which process is to be the subject of the patent, and is the process of preparing the known product alizarine from anthracine." Id. at 308-09.

This was not an instance of a new product describable only in terms of its process of manufacture. The BASF decision lends no support to today's en banc rule that every product claim that mentions a process step is always restricted to that process, with no exception no expedient, no preservation of the distinctions among forms of claim based on the nature of the invention."

152. It then proceeded to observe and acknowledge well-established principles of patent claims being construed on identical basis for validity as well as for infringement. This is evident from the following observations as rendered:-

> "Defying precedent, the en banc court adopts for all situations "the basic rule that the process terms limit product-by-process claims," maj. op. at 17, whether the product is novel or known, and whether or not the new product could not have been fully described by its structure alone. The court eliminates the long-accepted expedient for new products whose structure is not fully known. While the Scripps decision is the only decision that is mentioned as "expressly overruled," maj. op. at 17, Scripps is only one of many cases now discarded.
>
> The en banc majority's response to the dissenters is to state that "the inventor is absolutely free to use process steps to define this product" if its "structure is either not fully known or too complex to analyze," maj. op. at 19, but to eliminate the premise that the inventor thereby obtains a product claim, not a process claim. According to the majority, a patentee can continue to obtain product claims using process descriptors, but such product claims are treated as process claims for

infringement. The applicant would still have to demonstrate patentability of the new product as a product(independent of the process), while enforcement of the patent against an identical product would be limited to the infringer's use of the process steps used as a descriptor. For the first time, claims are construed differently for validity and for infringement.

It has been an inviolate rule that patent claims are construed the same way for validity and for infringement. See, e.g., Amgen Inc. v. Hoechst Marion Roussel, Inc., 324 F.3d 1313, 1330 (Fed. Cir. 2003) ("It is axiomatic that claims are construed the same way for both invalidity and infringement."); Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("Because the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); C.R. Bard, Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1363 (Fed. Cir. 1998) ("Claims must be interpreted the same way for determining infringement as was done to sustain their validity."); Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."); Beachcombers, International, Inc. v. WildeWood Creative Products, Inc., 31 F.3d 1154, 1163 (Fed. Cir. 1994) ("We have already interpreted the claims for purposes of assessing their validity. The same claim interpretation of course applies to the infringement analysis."); Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565, 1583 (Fed. Cir. 1991) ("claims must be construed the same way for validity and for infringement"); Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 882 (Fed. Cir. 1988) ("The claims of the '970 patent measure the invention at issue; thus, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses."); see also 5A Chisum on Patents §18.01 (2007) ("A fundamental tenet of patent law is that a claim must be interpreted consistently for purposes of infringement and validity."); id. §18.03[2][h] (collecting cases).

As interpreted for validity, the claims obtained under the expedient of necessity are product claims, and are subject to the requirements of novelty, unobviousness, and all other requirements for new products, independent of how the products can be made. My colleagues hold that these are product claims for validity, but process claims for infringement. Departure from the rule that forbids such deviation requires sound reason, and fuller exploration than the cursory brush-off dispensed by my colleagues.

I do agree with my colleagues that their logic is "simple." Maj. op. at 19.However, today's inventions are not simple. The needs of inventions of the past and present, and more so the future, are not simple. The public interest in invention and development of today's complex sciences, is not simple. The en banc court's "simple" hypothetical about "compound X, obtained by process Y," is simply irrelevant to the issues we must resolve. Scientists know that it is often easier to show that two products are the same, than to decipher their chemical or biological structure; for example, in the case at bar, comparing the X-ray diffraction patterns and absorption spectra could show that the products are the same, although their exact crystal structure is undefined. However, my colleagues announce that the only way to establish whether the accused compound is the same as the patented compound is by inquiring whether they were prepared by the same method. Maj. op. at 19-20 ("[W]hat analytical tools can confirm that the alleged infringer's compound is in fact infringing, other than a comparison of the claimed and accused infringing processes?"). That question has many answers, now stated to be irrelevant.

While the section of this opinion decided by the en banc court is largely directed to its reversal of precedent, the implementation of its ruling remains with the original panel. The panel decision enlarges the en banc ruling, further binding this court. The claims at issue state processes by which the new crystal form is "obtainable," although the specification states that other methods might be used. The panel rules that a claim "cannot capture a product obtained by or obtainable by processes other than those explicitly recited in the claims." maj. op. at 21, finding authority in BASF, which I have discussed ante. My colleagues thus continue to misapply the Court's ruling in BASF, where the Court stated repeatedly that the product in that case was a known product. BASF, 111 U.S. at 311 ("It was an old article."). In BASF the Court responded to the patentee's argument that it was entitled to cover all artificial alizarine made by any process, by observing that the patentee had not shown how the infringing and patented products "can be recognized," id. at 310, an aspect at the opposite pole from the case at bar, where the patentee provided elaborate details as to how the patented and accused crystal forms can be recognized.

The panel also states that "the applicant's statement in the file wrapper that 'the method of preparation . . . is not considered the heart of the present invention' should not be afforded undue gravitas." Maj. op. at 22. This too is an aberration of precedent, and is contrary to the many rulings of the Supreme Court and this court that afford due gravitas to the applicant's statement of what has been invented. See, e.g.,

BASF, 111U.S. at 308 ("It is very plain that the specification of the original patent, No. 95,465,states the invention to be a process for preparing alizarine, not as a new substance prepared for the first time, but as the substance already known as alizarine, to be prepared, however, by the new process, which process is to be the subject of the patent . . . ."); Plummer v. Sargent, 120 U.S. at 443 (quoting specification of companion patent, where inventor stated "My invention consists in a process of covering iron with a very thin coating of oil, and then subjecting it to heat, the effect of which is to leave upon the iron a firm film, which is very durable, and gives the iron a highly ornamental appearance, like that of bronze"). The Federal Circuit's emphasis on the importance of the specification has been repeatedly stated. E.g., Phillips v. AWH Corp., 415 F.3d1303, 1315 (Fed. Cir. 2005) (en banc) ("[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." (internal quotation marks omitted)).

The en banc court appears to misjudge the implications of its ruling, for the court states that it is now making available to "others the right to freely practice process Z [a different process] that may produce a better product in a better way." Maj. op. at 20. If others can indeed make a better product, this expedient presents no impediment. That is not the issue of this case. The issue is the right to make the same product, by making a process change that does not change the product. By now assuring that right, the exclusionary value of the claim to a new product is lost.

The purpose of the rule of necessity is to allow inventors of complex new products to obtain the patent scope to which their invention is entitled—the scope of the novel product they invented, no more and no less. The majority's change of law simply imposes unfairness as well as legal error on patent-supported advances."

153. The position in law as per the dissent was summarised as follows:-

"Precedent establishes that the correct construction of claims that recite process steps depends, like all claim construction, on what has been invented. No single rule fits all inventions. The construer must view the claims in light of the description of the invention in the specification, the prior art, and the prosecution history. In the complex law and practice of patents and inventions, the special expedient here of concern arises when the

> precise structure of a new product is not known from the information available when the patent application was filed. The law has enabled and endorsed this expedient of describing a product in order to claim it as a product, whereby validity and infringement are determined as a product independent of any process term that was used to aid in defining the product. This expedient does not enlarge patent scope; it simply permits patenting what has been invented. A narrow but clear body of law has evolved to accommodate this need of complex technologies. This entire body of law is today overturned, sua sponte and without a hearing, without any participation of those affected, without identification of the intended benefits. I respectfully dissent from the en banc court's rulings, as well as the procedure by which they were reached."

154. Lourie J. who joined the dissent held that if a product is old, it would be unpatentable and thus the decision in BASF liable to be understood bearing the aforesaid facet in mind. Commenting upon the unsustainability of the distinction sought to be created between invalidity and infringement, the learned Judge observed as follows:-

> "I respectfully dissent from the court's en banc holding in Section III. A. 2 that product-by-process claims always require use of the recited process in order to be infringed.
>
> I agree that there is substantial Supreme Court precedent that holds that product by-process claims require use of the recited process for there to be infringement. However, many of those cases applied overly broad language to fact situations involving old products or used vague language that makes it difficult to determine whether the products were old or new. Clearly, however, when a product is old, a product-by-process claim cannot be interpreted as a claim to the product made by any means. The product is old and unpatentable per se. BASF in fact involved an old product. See Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 311 (1884) ("It was an old article.").
>
> There is arguably a different situation that should apply to chemical biological products today than to mechanical products of more than a century ago. When a product is new and the inventor claims it by a process of preparation, I fail to see why the product-by-process claim should not be interpreted as a product claim that can be infringed even when the product is made by means other than that recited in the claim. Supreme

> Court precedent dealing with old products, while utilizing broad language, does not foreclose that possibility. The Court years ago did not have occasion to consider today's innovations or decide whether a distinction should be made between a new chemical-biological product and an old product made by a new process.
>
> And there may be differing results depending upon the exact wording of a claim at issue. For example, a claim reading "when made by" might only be infringed when the recited process is used by the accused, as it is situational. On the other hand, a claim reading "obtainable by" refers to capability, so it might not require use of the process to infringe. "Obtained by" is ambiguous. Bright lines have their uses, but judging should take account of differing circumstances. In addition, of course, in order to sustain any claim for infringement, a patent owner must prove that an accused product is the same as that covered by an asserted claim. If the reason a product was claimed by its process was that its structure was unknown, then, if, at the time infringement is asserted, there still is no means to ascertain structurally whether the accused product is the same as that claimed, the infringement claim fails. However, that should not mean that a new product claimed by a process of preparation cannot ever be infringed when made by another process.
>
> It may be that with today's analytical techniques there is little need for product-by- process claims. After all, claim 1 of the Abbott patent is a claim to a compound, not only by name, but also by certain of its characteristics. A claim to a product defined by its characteristics or properties surely is a proper claim.
>
> However, product-by-process issues still seem to come before us and I would make a distinction between old products and new products in interpreting product-by-process claims. Accordingly, I respectfully dissent from the court's en banc holding."

155. The decision in *Abbott Laboratories* rendered by the US Federal Court, though not binding upon us, is a precedent which evidences the conflicting and diametrically opposing positions which were taken. As would be manifest from the various precedents which we have had an occasion to consider, the position which has been taken by the majority in *Abbott Laboratories* does not appear to have found acceptance in any other jurisdiction. In fact, and as the appellants themselves had pointed

out even the Japanese Supreme Court did not accept that process terms are limiting or that they remove the focus from the inventive product itself. In fact the Court spoke of the "double standard" approach which would have to be adopted if *Abbott Laboratories* were to be followed and distinct principles applied to try infringement actions. We deem it apposite to refer to the following passages from the decision of that Court in **2012 (Ju) 1204, Minshu Vol. 69 No.4**[36]:-

> "**1.** In this case, the appellant of final appeal, who holds a patent right for an invention of a product based on a claim which recites the manufacturing process of the product, generally referred to as a "product-by-process claim," alleges that the medicine manufactured and sold by the appellee of final appeal infringes the appellant's patent right, and seeks an injunction against the appellee to stop it from manufacturing and selling the medicine in question and demands the disposal of the same. The appellee contends, inter alia, that the appellee's medicine does not fall within the technical scope of the invention covered by the appellant's patent. The point at issue in this case is how to determine the technical scope of the patented invention in the case where a claim of a patent for an invention of a product recites the manufacturing process of the product.
>
> **2.** The outline of the facts determined by the court of prior instance is as follows.
>
> (1) The patent in question
>
> The appellant holds a patent for an invention titled "pravastatin sodium substantially free of pravastatin lactone and epipravastatin, and compositions containing the same" (Patent No. 3737801; the number of claims: 9; hereinafter referred to as the "Patent").
>
> (2) The invention in question
>
> Claim 1 of the Patent (hereinafter referred to as the "Claim") is as described below (hereinafter the invention described in the Claim is referred to as the "Invention").
>
> "Pravastatin sodium prepared by a process comprising the steps of:

[36]https://www.wipo.int/wipolex/en/text/584262

(a) forming an enriched organic solution of pravastatin;
(b) precipitating pravastatin as its ammonium salt;
(c) purifying the ammonium salt by recrystallization;
(d) transposing the ammonium salt to pravastatin sodium; and
(e) isolating pravastatin sodium, and containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava."

(3) The appellee's product
A. The appellee manufactures and sells medicine named pravastatin Na tablets, 10mg, "KH" (former name: pravastatin Na tablets, 10mg,"Merck"; hereinafter referred to as the "appellee's product").
B. The appellee's product contains pravastatin sodium that contains less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava. The manufacturing process of the appellee's product does not contain, at least, the step of "a) forming an enriched organic solution of pravastatin," which is stated in the Claim.

3. The court of prior instance dismissed the appellant's claim, holding as follows.

(1) When a claim of a patent for an invention of a product recites the manufacturing process of the product, the technical scope of the invention should be determined as being limited to products manufactured by the manufacturing process recited in the claim, except when there are circumstances where it was impossible or difficult to directly define the product subject to the invention by means of its structure or characteristics at the time of the filing of the application.

(2) Since such circumstances mentioned in (1) above cannot be found with regard to the Invention, the technical scope of the Invention should be determined as being limited to products manufactured by the manufacturing process recited in the Claim. The manufacturing process of the appellee's product does not contain, at least, the step of "a) forming an enriched organic solution of pravastatin," which is stated in the Claim, and hence the appellee's product does not fall within the technical scope of the Invention.

4. However, we cannot affirm the criterion mentioned in 3.(1) above, which was presented by the court of prior instance, and then, we also cannot affirm the determination mentioned in 3.(2)

above, which was made by the court of prior instance based on that criterion. The reasons for this conclusion are as follows.

"(1) The recitation of a claim attached to a patent application plays a role of the basis for determining the technical scope of a patented invention (Article 70, paragraph (1) of the Patent Act), and also for identifying the gist of the invention claimed in a patent application, which serves as the premise for examining the requirements of patentability prescribed in Article 29 of said Act (see 1987 (Gyo-Tsu) No. 3, judgment of the Second Petty Bench of the Supreme Court of March 8, 1991, Minshu Vol. 45, No. 3, at 123). A patent is to be granted for an invention of a product, an invention of a process or an invention of a process of producing a product. If a patent has been granted for an invention of a product, a patent right relating to that patent is effective against any products that have the same structure, characteristics, etc. as those of the product subject to the invention, irrespective of the manufacturing processes of these products.

Consequently, it is appropriate to construe that even when a claim of a patent for an invention of a product recites the manufacturing process of the product, the technical scope of the patented invention should be determined as being limited to products that have the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim.

(2) Under Article 36, paragraph (6), item (ii) of the Patent Act, the recitation of a claim must meet the requirement that the claimed invention is clear. The patent system is designed to grant a patent right, which is an exclusive right, to a person who has disclosed his or her invention, thereby protecting the invention for the interest of the patentee, while enabling a third party to understand the content of the patented invention, with the ultimate purpose of promoting the utilization of inventions to encourage inventions, and thereby contributing to the development of industry (see Article 1 of the Patent Act). The provisions of Article 36,paragraph (6), item (ii) of said Act can be understood as requiring clarity of the claimed invention because of such purpose of the patent system. From this viewpoint, in cases where a claim of a patent for aninvention of a product recites the manufacturing process of the product, without exception, if the technical scope of the patented invention is determined on the assumption that a patent right relating to that patent is effective against any products that have the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim, this could be unfairly prejudicial to the interest of a third party and would be problematic. More specifically, when claim of a patent for an invention of a product recites the manufacturing process of the product, it is generally unclear what structure or characteristics of the product are represented by the manufacturing process, or whether the technical scope of the

patented invention is limited to products manufactured by the manufacturing process, although the subject matter of the invention is the product, and this would prevent those who read the recitation of the claim, etc. from clearly understanding the content of the invention and make it impossible for them to predict the scope of the exclusive right to be conferred to the patentee, leading to an inappropriate situation.

On the other hand, in a claim of a patent for an invention of a product, the applicant is usually supposed to directly define the product by clearly reciting its structure or characteristics. However, there may be cases where, depending on the specific content, nature, etc. of the invention, it is technically impossible to analyze the structure or characteristics of the product at the time of the filing of the application, or where it is utterly impractical to require the applicant to define the product in such manner because, in light of the nature of a patent application that needs to be handled speedily, etc., the work to define the product could require excessive economic costs and time. Assuming so, it is inappropriate to prohibit reciting the manufacturing process of a product in a claim of a patent for an invention of a product in any case, but rather it must be said that if there are such circumstances as mentioned above, it would not be unfairly prejudicial to the interest of a third party to determine the technical scope of the patented invention as referring to products that have the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim.

According to the above, it is appropriate to construe that when a claim of a patent for an invention of a product recites the manufacturing process of the product, the recitation of the claim should be held to meet the requirement that the claimed invention is clear as prescribed in Article 36, paragraph (6), item (ii) of the Patent Act, only if there are circumstances where it was impossible or utterly impractical to directly define the product subject to the invention by means of its structure or characteristics at the time of the filing of the application."

156. It would also be profitable to take note of the following observations appearing in the concurring opinion of Chiba Katsumi J. :-

"**3.** According to the view explained above, I would examine the details of exceptional circumstances due to which a product-by-process claim should be permitted.

(1) In the present case, this court (majority opinion) states that such circumstances can be found if "there are circumstances

where it is impossible or utterly impractical" to define the product subject to the invention, and the details of these circumstances are explained in the majority opinion. The term "impossible" referred to therein means the case where it is impossible mainly from a technical perspective for a person ordinarily skilled in the art at the timeof the filing of the application to define the product subject to the invention by analyzing its structure or characteristics (the term "characteristics" as used here means characteristics that are appropriate and significant in distinguishing the product in question from other products in the course of determining the novelty and involvement of an inventive step in the invention). The term "utterly impractical" referred to in the majority opinion assumes the case where, rather than from a technical perspective, the work to define the product could force a person ordinarily skilled in the art at the time of the filing of the application to spend time and costs to an extent that is impractical in terms of profitability and therefore it would be too cruel to require such person to perform such work while trying to obtain a patent in the face of the rapid advancement of technology and fierce competition on a global scale. Although the meaning of the latter term is not firmly established, the guideline for considering what case would actually fall under the meaning of the latter term will be made clear as court cases addressing this issue are accumulated in the future.

(2) The third criterion adopted in the JPO's current examination practice, i.e., "where it is inappropriate," covers too broad a range because it relies too much on an aspect of value judgment and its substance is unclear. Furthermore, even when it is not so difficult to define the product by means of its structure, etc., this criterion could lead to allowing the applicant to recite the manufacturing process in the claim merely for the purpose of making it easier to understand the constitution of the invention. At any rate, applying this criterion could result in the outcome being inconsistent with the purpose of admitting the concept of a product-by-process claim, and therefore it cannot be held to be reasonable.

If the applicant intends to make it easier to understand the constitution of the invention, it would be sufficient to describe the manufacturing process in the "detailed explanation of the invention," rather than reciting it in a claim, and the applicant should take this approach.

4. I would comment on the patent practice in the future and the conventional handling of a product-by-process claim.

(1) Conventionally, in the examination of a product-by-process claim at the time of the filing of an application, the JPO has permitted the application with such claim by loosely applying the requirement of impossible, difficult or inappropriate circumstances, without conducting substantive examination on this point. In the future, on the contrary, if a claim recites the manufacturing process, the JPO is expected in the examination process to first confirm that the application contains a product-by-process claim, and then request the applicant to allege and prove that there are impossible or impractical circumstances, and if the applicant fails to submit sufficient allegation and proof on this point, the JPO is to issue a decision to refuse the application. If the applicant wishes to avoid the refusal, the applicant would need to apply for a patent for the same invention as an invention of a process for producing a product as well (Article 2, paragraph (3), item (iii) of the Patent Act).

(2) In this respect, according to the criterion presented in the judgment of the Grand Panel of the Intellectual Property High Court, which is the court of prior instance of the present case, it is assumed that the JPO, in its examination practice, does not reject a product-by-process claim by reason of the failure to meet the clarity requirement irrespective of whether or not there were circumstances where it was impossible or difficult at the time of the filing of the application to directly define the scope of the invention of the product by means of the structure, etc. of the product (hereinafter referred to as "impossible or difficult circumstances"), and based on this assumption, the JPO adopts the approach that categorizes a product-by-process claim into two types, in that, both when identifying the gist of the invention and when determining the technical scope of the patented invention, the JPO in principle follows the manufacturing process limitation theory by regarding the claim as a pseudo product-by-process claim, whereas the JPO follows the product identity theory if the claim is a genuine product-by-process claim for which impossible or difficult circumstances exist. This approach, in light of the spirit of Article 1, etc. of the Patent Act, permits a claim that defines a product by means of its manufacturing process, and treats such claim as not violating Article 36, paragraph (6), item (ii) of said Act. It can be described as representing the JPO's view reached through its elaborate efforts to pursue a realistic way of handling a product-by-process claim in accordance with both the principle of said Act and the JPO's examination practice.

However, this view is somewhat inconsistent with the precedents of this court in which the court seems to have adopted the product identity theory to construe a product-by-

process claim (1997 (Gyo-Tsu) No. 120, judgment of the Third Petty Bench of the Supreme Court of September 9, 1997, not officially published, 1997 (Gyo-Tsu) No. 121, judgment of the Third Petty Bench of the Supreme Court of September 9, 1997, not officially published, 1998 (O) No. 1579, judgment of the Third Petty Bench of the Supreme Court of November 10, 1998, not officially published). Furthermore, while whether the product-by-process claim in question is a genuine or pseudo one remains unclear until the court presents its view on this point, the scope of the claim would greatly differ depending on this distinction and might disagree with what the applicant intended. The scope of a right to be conferred by a patent would also greatly differ depending on whether the invention is defined by a genuine or pseudo product-by-process claim, but this point remains unclear, making it difficult for a third party to predict the scope of the right appropriately. This problem is ultimately attributed to the scope of the patent being unclear and unspecific, which should be held to be in violation of Article 36, paragraph (5), and paragraph (6), item (ii), etc. of the Patent Act. Moreover, according to the JPO's view, it would be necessary in the examination practice to make a clear distinction as to whether the product-by-process claim is a genuine or pseudo one before permitting the patent application because the scope of the claim, etc. could differ depending on this distinction. As a result, the JPO would have to be very careful in carrying out the examination and hence would have to bear a greater burden, and this would be highly likely to cause delay in examination.

(3) In light of the abovementioned problems posed by the court of prior instance, the majority opinion presents a view that will help establish the examination practice in which the JPO will strictly consider whether there are circumstances where a product-by-process claim should be permitted, while taking into account the principal purpose of the concept of this type of claim, and will advise the applicant to apply for a patent for an invention of a process for producing a product if the application with a product-by-process claim is likely to be refused due to the absence of such circumstances. This will change the conventional examination practice in that the JPO will be expected to substantively examine the requirement for permitting a product-by-process claim as a patent for substance. However, the applicant would doubt how common it has been to apply for a patent with a product-by-process claim rather than an ordinary patent with regard to an invention of a product even when the product can be defined by means of its structure (when impossible or impractical circumstances do not exist), and if it is truly "impossible" or "utterly impractical" to define the product by means of its structure, etc., the applicant would not find a

great burden in alleging and proving this point (for example, in the field of life science, a claim which recites a cell, etc. created by a new genetic engineering technique would not be rejected on the grounds of the absence of circumstances where it is impossible or utterly impractical to define such a cell, etc. by its structure, etc. at the time of the filing of the application). In the examination process, since there is a limit due to the nature of the task to the applicant's potential to prove the existence of such circumstances voluntarily and strictly, the JPO will not be able to strictly require the applicant to do so and would be very likely to find the existence of such circumstances unless there is a reasonable doubt. In this meaning, it is very likely that the applicant would not have to worry so much.

(4) Next, it is also expected that requests for invalidation trials will be filed or the defense of invalidity will be raised in infringement suits in relation to patents with product-by-process claims that have already been granted and registered without, in principle, going through the test in terms of the existence of impossible or impractical circumstances in the examination process. However, if the applicants of these patents were unable to establish the existence of impossible or impractical circumstances at the time of the filing of the applications (which means that the applicants easily chose to file product-by-process claims in which the products were defined by the manufacturing processes although the products could have been defined by their structure, etc.), it is inevitable that their patents would later be invalidated. However, this situation results from the conventional examination practice in which the JPO has loosely examined and permitted product-by-process claims, and it is not attributable to the applicants alone. To avoid such a situation, procedures such as a request for correction (Article 134-2 of the Patent Act) in a patent invalidation trial and a request for a trial for correction (Article 126 of said Act) may be helpful. How these procedures will actually be handled is an issue to be addressed in the future."

157. The only reservation which appears to have been harboured was Yamamoto Tsuneyuki J who doubted the practical application of the "impossible or utterly impractical" test for admission of product-by-process claims as formulated by the majority of that Court. We deem it appropriate to extract the following parts of that opinion:-

"**2.**What patent practice is acceptable on a global scale? I would explain this point based on my understanding, taking the patent practice in Japan as an example.

As a result of the abovementioned amendment to the Patent Act, the patent practice at the JPO has changed so that an examiner will not refuse an application by reason of the failure to conform to the provisions of the amended clause, based on the idea that it is inappropriate for an examiner to examine whether all the matters necessary for defining an invention are recited in a claim, against the will of the applicant who drafted the claim at his or her own discretion. Accordingly, under the existing system of the Patent Act, it is up to the applicant to choose a function claim, product-by-process claim or whatever form of claim to define the invention for which a patent is sought, whereas the invention defined by such claim will not be patented if it falls under any of the items of Article 49 of the Patent Act (reasons for refusal), and even where it is patented, the patent will be invalidated if it falls under any of the items of Article 123 of said Act (grounds for invalidation). Consequently, according to the purpose of the legal amendment in 1994, it seems to me that the JPO has been very careful about refusing an application or invalidating a patent by assessing what is recited in a product-by-process claim to be unclear on the grounds of, in a sense, procedural matters---whether the claim in question meets the formal definition of a product-by-process claim, or what kind of product-by-process claim it is---, insomuch as the applicant him/herself chose this type of claim. I consider that this practice at the JPO reflects correct interpretation and application of law.

To my understanding, according to the JPO's Examination Guidelines, an application with a product-by-process claim may be refused in the following two cases.

Case 1 is that a product-by-process claim fails to meet the clarity requirement and is rejected due to violation of Article 36, paragraph (6), item(ii) of said Act (referred to in Article 49, item (iv) and Article 123, item (iv) of said Act) (Examination Guidelines, Part I, Chapter 1, page 15, [2]Typical examples where the claimed invention is considered to be unclear). More specifically, an application with a product-by-process claim may be refused if [i] the claimed invention is unclear because the manufacturing process (e.g. starting material, manufacturing steps) recited in the claim cannot be understood, or [ii] the claimed invention is unclear because the characteristics of the product (e.g. structure and nature)recited in the claim cannot be understood (for example, when the description includes only

process-related characteristics (e.g. high yield or efficiency in manufacturing can be achieved by the manufacturing process in question)). In these cases, it cannot be said that the invention of a product is defined by a product-by-process claim. In other cases, as long as the invention of a product is defined by a product-by-process claim, the examiner permits the claim as-is and then examines the requirements of patentability such as novelty and involvement of an inventive step. This practice applies even when part of what is recited in a product-by-process claim is unnecessary. I understand that it is common practice on a global scale.

Case 2 is that a product-by-process claim fails to meet the novelty requirement and is rejected due to violation of Article 29, paragraph (1), item(iii) of said Act (Examination Guidelines, Part II, Chapter 2, page 8). In this case (where it is clear that the invention claimed in a patent application is a product because it is recited in a product-by-process claim which is composed in the form of a noun that refers to a "product"),what is recited in the claim is construed as referring to the product itself that is finally obtained. Accordingly, the novelty of the claimed invention is denied when the same product can be manufactured by any manufacturing processes other than the one recited in the claim and this product is publicly known.

In brief, in Case 1 [i], an application with a product-by-process claim is refused if the invention cannot be understood from what is recited in the claim, as in the case of other forms of claim. In Case 1 [ii], an application with a product-by-process claim is refused if the invention is unclear when viewed as an invention of a product because the claim only recites process-related characteristics, such as high yield or efficiency in manufacturing achieved by the process in question, and the characteristics of the product in question are unclear (which means that the invention should have been claimed as an invention of a process).In Case 2, an application with a product-by-process claim is refused due to lack of novelty and an inventive step because the product itself is publicly known or can be easily invented from publicly known art.
As explained above, although the applicant is free to choose what to recite in a claim, an application with a product-by-process claim that should have been refused is eventually refused through the necessary and sufficient application of the clarity and novelty requirements. If such a claim is patented by mistake, the patent will be invalidated under the same criteria as those described above. I consider that the same should be applied to the cases under Article 104-3 of said Act.

3. However, the majority opinion in this judgment could result in fundamentally undermining the abovementioned interpretation of the Patent Act and patent practice. I would have no particular objection if it is in the right direction, but to me, it does not at all seem to be right. The majority opinion (4.(2)) explains that a product-by-process claim regarding an invention of a product must be clearly written, in reference to the purpose of Article 1 of the Patent Act and the provisions of Article 36, paragraph (6), item (ii) of said Act. This is right as a general theory. However, it is often the case that an invention of a product cannot be clearly recited in a claim other than a product-by-process claim. In particular, in the case of an invention of a product that has novelty, it would be very easy to understand the invention if the applicant describes the process by which the product is made. However, if the applicant tries to describe the product by means of its structure or characteristics, the description would, no doubt, need to be expressed with complicated concepts and terms. In that case, the applicant would have to spend unnecessary time and cost and would miss the chance to file an application at the right time, and what is more, such description would rather be hard to understand not only for the examiner but also for a person ordinarily skilled in the art, which is contrary to the clarity requirement. For example, with regard to an invention relating to a new cell in the field of life science, if this invention is described by a product-by-process claim in such a manner as "a cell produced by a certain method of injecting a certain gene into a certain cell," the description of the claim would be very easy to understand for a person ordinarily skilled in the art. If, to the contrary, the cell produced by such process is required to be described based on its structure or characteristics, although it may not be completely impossible to do so by spending considerable cost and time, the description of the claim regarding the cell that has been finally elaborated through such effort might in most cases be dry-as-dust, pointless and incomprehensible to anyone. It is easy to imagine that an application with such a claim will be refused due to the failure to meet the clarity requirement. Such a consequence goes further away from the ideal of the Patent Act, i.e., the achievement of harmonization between protection of inventions and public use thereof.

On this point, the majority opinion states, "there may be cases where … it is technically impossible to analyze the structure or characteristics of the product at the time of the filing of the application, or where it is utterly impractical to require the applicant to define the product in such manner because, in light of the nature of a patent application that needs to be handled speedily, etc., the work to define the product could require

excessive economic costs and time," thus it appears to intend to permit a product-by-process claim although in an extremely limited manner. However, it concludes, "the claim should be held to meet the requirement that the claimed invention is clear as prescribed in Article36, paragraph (6), item (ii) of the Patent Act only if there are circumstances where it was impossible or it was utterly impractical to directly specify the product subject to the invention by means of its structure or characteristics at the time of the filing of the application." If this interpretation applies, there would be almost no chance for a product-by-process claim to be permitted.

This issue reminds me of recent important inventions in the field of life science, which relate to stem cells produced by new genetic engineering techniques. In most cases, when a patent application is filed for such an invention by claiming it as an invention of a product, the claim would be in the form of a product-by-process claim. Then, according to the majority opinion mentioned above, the applicant, when drafting a claim, would first need to consider if it is possible to directly define the product by means of its structure or characteristics, for fear that the application or patent with that claim would be refused or invalidated just because the claim is in the form of a product-by-process claim. However, it is not at all easy for the applicant to perform the work to define the product and prove the fact as required according to the criterion presented by the majority opinion, that is, "there are circumstances where it was impossible or it was utterly impractical to directly define the product subject to the invention by means of its structure or characteristics at the time of the filing of the application" (hereinafter referred to as the "criterion of impossible or impractical circumstances"). It seems to be rather unrealistic just to imagine such work or proof, but there is no evidence, either, that it is impossible to do so. Meanwhile, while taking much time to do such a thing, the applicant would lag behind in fierce global competition with other applicants under the first-to-file principle, so the applicant would feel pressed to file a patent application. Presumably, the applicant in such a situation would take the decision to file an application with a product-by-process claim because of being unable to express the product by means of its structure or characteristics, although he or she is not firmly confident whether or not such decision was right. Then, in the examination or trial procedure, the application or patent with a product-by-process claim would be tested as to whether it should be refused or invalidated by reason of the failure to conform to the criterion of impossible or impractical circumstances. However, since this criterion of impossible or impractical circumstances is too ambiguous and vague to grasp,

it seems to me to be very difficult to interpret and apply the criterion in a stable and uniform manner. Moreover, seeing that matters such as how an assessment as to circumstances where "it was impossible or utterly impractical" would be made by whom and by what criteria have not been clearly indicated at all, I would say that the concept of circumstances where "it was impossible or utterly impractical" is almost equal to referring to circumstances where it was "impossible." I am concerned that, as a result, most patent applications claiming inventions of products with product-by-process claims would be refused by reason of the failure to meet the clarity requirement. This could bring about what is called the chilling effect, driving all product-by-process claims out of Japanese patent applications even when these claims are truly necessary, and impeding protection of inventions. I am also concerned that since the failure to conform to the criterion of impossible or impractical circumstances could be the ground for invalidating the existing patents, the validity of a number of patents with product-by-process claims that have already been granted would be challenged more frequently in litigation. When these patents were granted, there was no room for the applicants to be conscious of the criterion of impossible or impractical circumstances. Such background should be taken into careful consideration in such litigation.

It is true that the perspective of preventing the interest of a third party from being unfairly prejudiced is as important as the perspective of protecting inventions, as pointed out in the majority opinion. The essential nature of patents can be described as residing in balance between these two perspectives. However, there is the risk that the application of the criterion of impossible or impractical circumstances presented in the majority opinion would lead to the complete failure to achieve the protection of inventions, which is what I am most concerned about.

In the current patent practice, when each claim in a patent application is composed in the form of a noun that refers to a "product" rather than a "process," it is clear that protection by a patent for an invention of a product is sought even if the relevant claim is a product-by-process claim. Then, the application is eventually refused if the product finally obtained by the process recited in the claim is found to lack novelty and an inventive step, that is, it is a publicly known product. Accordingly, a third party would have to pay attention only to patent applications that claim new products, in which case the third party's burden of caution would be mitigated to a considerable degree. In other words, in cases such as where a person ordinarily skilled in the art would have been unable to assume the specific product manufactured by the manufacturing process recited in the claim even by taking into consideration the common general technical

knowledge available at the time of the filing of the application, it would suffice to treat this as the premise for determining the novelty and involvement of an inventive step in the claimed invention. Contrary to this, according to the majority opinion, when a claim is composed in the form of a product-by-process claim that fails to meet the criterion of impossible or impractical circumstances, the application or patent with such claim would be refused or invalidated without exception on the grounds of the failure to meet the clarity requirement because of this claim form. I consider that this consequence is far outside the range of the conventional interpretation of Article 36, paragraph (6), item (ii) of the Patent Act and it obviously constitutes misinterpretation of law.

5. Conventionally, the issue of identifying the gist of the invention and the issue of determining the technical scope of the patented invention were addressed separately, the former by the JPO and the latter by the court. Since these issues, when brought to litigation, were dealt with in separate cases, I presume that it did not appear to be so strange even if these cases ended up with inconsistent conclusions. However, as a result of the introduction of Article 104-3 to the Patent Act through the amendment in 2004, it has become possible to raise the defense of invalidity of a patent in the litigation proceedings in which patent infringement is claimed. Accordingly, it has come to be considered to be unreasonable for the same claim to be construed differently, and the double standard that previously existed is now being eliminated. This is the right direction. The "gist of the invention" involved in determining patentability and the "technical scope of the patented invention" involved in determining infringement must be consistent with each other as claim construction.

Having said that, if the "technical scope of the patented invention" is assumed as the first place to start, and in the stage of identifying the "gist of the invention," emphasis is placed on a sort of a procedural issue, i.e. whether the claimed invention meets the criterion of impossible or impractical circumstances, and a patent is refused from the beginning by applying the clarity requirement, such practice has gone too far as claim construction. In light of the purpose of the amendment to the Patent Act in 1994, if the claimed invention can be defined based on the content of a claim that the patent applicant has chosen him/herself, a patent should be granted as long as the invention has novelty and an inventive step. This is irrelevant to whether a product-by-process claim is contained in a patent application. This is the stage of identifying the gist of the invention.

In such case, a question may be raised as to the interpretation of Article 70 of the Patent Act in connection with the handling of a product-by-process claim. In this respect, I consider that the manufacturing process recited in a claim of a patent for an invention of a product (a claim composed in the form of a noun that refers to a "product") should be construed as being recited with a view to defining the product itself that is made by the manufacturing process, rather than as being recited to limit the scope of the patent by means of the manufacturing process. Such claim construction is made on the basis of the wording of the claim. In other words, when the manufacturing process is recited in a claim of a patent for an invention of a product, this fact can be construed as the applicant's intention to seek protection for the invention of the product itself, and such manner of construction should be the principle.

Next, with regard to a product-by-process claim, it is necessary to admit that there may be exceptional cases where the issue of determining the technical scope of the patented invention cannot be considered in the same manner as considering the issue of identifying the gist of the invention addressed in response to the defense of the invalidity of the patent. Claim construction performed by the court in an infringement suit is intended for the purpose of determining the scope of legal protection of a patent right already granted. On the other hand, claim construction performed by the JPO in the examination and trial procedures is intended for the purpose of assessing whether or not to grant a patent for the claimed invention (in the examination procedure) or assessing whether or not a patent already granted should have been granted at all (in the trial procedure). Thus, purposes are different between claim construction by the court and that by the JPO, and it may be inevitable that the court and the JPO reach different constructions. In this sense, a product-by-process claim should be regarded as an exceptional case where the technical scope of the patented invention determined in an infringement suit may be inconsistent with the gist of the invention identified by the JPO. This view could lead to the consequence that for some product-by-process claims, the technical scope of the patented invention determined by the court, within which a patent may be enforced, is narrower than the gist of the invention identified by the JPO. However, this results from the applicant having chosen a product-by-process claim, and hence it is an inevitable consequence. Therefore, as is currently done in some actual cases, a reasonable conclusion may be drawn by construing the technical scope of the patented invention, which is based on a patent for an invention of a product expressed in the form of a product-by-process claim, as being substantially limited to the manufacturing process, by applying the doctrines

> of claim construction already established, such as the doctrine of estoppel and the doctrine of intentional exclusion."

158. On first principles, there appears to be no valid justification to ignore the invention merely because the applicant may have chosen to fully describe the product with reference to the means of manufacture. The invention neither ceases to exist nor can it be ignored as long as it is conceded that the claim relates to a product which was novel and unknown in the prior art. In fact, if the claim did not pertain to an invention, the application itself would not have been granted. This since the patent guidelines in unequivocal terms stipulate that it is incumbent upon the applicant to establish the patentability of the product and not the novelty of the process. We fail to find any justification to hold or recognise the law to be that while an inventive characteristic of a product sets it apart from claimed subject matter and the prior art, the same should be disregarded when it comes to infringement analysis. There is an imperative necessity to assess novelty and the scope of the patent right based on a consistent criterion. The acceptance of the argument canvassed by the respondents would compel us to recognise the examination process being subject to a set of rules distinct and contrary to the principles which would apply to infringement analysis. The patentability and novelty of a product thus becomes triable based upon to two separate and distinct set of rules. This would invariably result in the creation of an incongruous and anomalous situation. It essentially bids us to recognise a position where while the patent may validly be accepted to be a product at the stage of grant, it becomes confined to a process for the purposes of examining infringement. This submission proceeds on the incorrect assumption of the patentee having voluntarily chosen to surrender a valuable claim to a product. We thus

find ourselves unable to concur with the *Abbot* rule of process terms limiting the scope of protection that can be claimed in an infringement action. There cannot be shifting lines of protection-one which would imbue the examination process and another completely distinct and discordant test for infringement. If the product is discernible, unobvious and novel, it cannot be ignored in the course of trying an infringement action. The submissions based on *Abbott Laboratories* proceed on the premise that a product-by-process claim would render the notional audience incapable of discerning the true intent of the patentee. That, however, is a question which relates to claim construction. The aforenoted submission also fails to bear in consideration that the onus of proving infringement lies on the patentee. It would thus be incumbent upon the patent holder to establish that what was claimed was in fact a product and the claims read together with the specifications lead us unerringly towards that conclusion. In any case, the apprehended confusion or lack of clarity would not justify accepting the principle to be that for the purposes of evaluating an allegation of infringement one must necessarily proceed on the basis that process terms limit or deprive product-by-process claims of their essence. We are thus of the firm opinion that the theory of a distinct set of rules being applicable to infringement actions is wholly incorrect and untenable.

159. In our considered opinion, once the learned Judge had accepted FCM to be a product-by-process claim, there existed no justification to confine or whittle down the width of protection claimed by that product to a particular process. If the validity of the patent had not been assailed, the learned Judge was bound to answer the issue of infringement *de hors* the process terms. This since the invention which

was claimed was not with respect to the process but for the product itself. If the product manufactured by the respondents was FCM, the mere adoption of a tweaked mode or method of manufacture would have been wholly irrelevant. If FCM were not a novel product, the manufacturing process recited by the appellants would have been insufficient to sustain a patent claim, at least in the form of a product-by-process claim. As has been consistently held, the mere adoption of a novel process is considered inadequate for the grant of a patent unknown in the prior art. In any case the acceptance of the limiting argument would necessarily result in relocating the patent in the category of a process claim even though the patent stands granted principally to a product.

160. As was observed earlier, a process patent accords protection to the process and to the products obtained by that process alone. An infringement of such a patent would occur only if the process was repeated and directly resulted in the creation of an identical product. It is for this reason that the statute uses the expression *"obtained directly by that process…."*. A product patent on the other hand is concerned with an article which is novel and wholly detached from the process of manufacture. We find that whether it be a question of validity or infringement, the patentability of a product can always be assailed irrespective of the process terms. In fact, if a defense of invalidity were to be raised in a suit for infringement, it would be open for a defendant to assert that the patent has been wrongly granted either on the ground of a lack of novelty or otherwise being unpatentable. This in light of the right conferred by Section 107 in unambiguous terms. Such a challenge would itself be addressed upon the product itself. That challenge would not rest upon the process terms at all. It would be incumbent upon such

a defendant to prove that the claim does not relate to a novel or inventive product and that assertion would clearly not be influenced by the mere recitation of the process terms. In our considered opinion, a product-by-process claim would necessarily have to be examined on the anvil of a new and unobvious product irrespective of the applicant having chosen to describe the invention by referring to a process of manufacture.

161. The mere adoption of the product-by-process format would not result in a novel product being downgraded to Section 48(b) of the Act. It would inevitably have to be tested on principles enshrined in Section 48(a). It is this aspect of significance which convinces us to hold that the mere usage of process terms cannot be accepted as limiting nor does there appear to be any justifiable rationale to countenance or accept the distinction between validity and infringement as suggested in the impugned judgement. If a product be already known in the prior art**,** it would clearly not be entitled to patent protection. A process claim on the other hand would be confined to the novelty and unobviousness of the process in respect of which protection is claimed. If the rule of necessity were to compel the applicant to submit an application embodying a product-by-process claim, there would appear to be no justification to stultify the extent of protection.

162. The learned Judge while seeking to identify the basic precepts pertaining to claim construction had referred to the decision in *F. Hoffmann-La Roche* handed down by a Division Bench of the Court. It is however relevant to note that the principles which were ultimately culled out in Para 67 of *F. Hoffmann-La Roche* do not deal with product-by-process claims at all. However, the learned Judge has proceeded to observe that IN'536 though a product-by-process claim

would be limited to the product obtained by the specified process based on a reading of that decision. This conclusion is sought to be sustained on the basis of the *"first principles"* indentified in *F. Hoffmann-La Roche*. The aforesaid conclusion is patently unsustainable since *F. Hoffmann-La Roche* cannot possibly be construed as being an authority which dealt with the interpretation of product-by-process claims nor do any of the conclusions set out in Para 67 support the view ultimately expressed by the learned Judge. The said decision cannot be accepted to be an authority for the proposition that process terms limit the claim of protection.

163. The arguments addressed on behalf of the appellants and turning upon the meaning to be ascribed to the phrase *"obtainable by"* were also negatived by the learned Judge referring to *Hospira UK Limited*. The learned Single Judge, however, ignores that *Hospira UK Limited* related to an *"obtained by"* claim and which in that sense would clearly fall within the scope of Section 48(b**)** of the Act. The learned Judge completely overlooks, ignores and fails to render any consideration on the suit patent being prefaced by the words *"obtainable by"*. The impugned judgment also fails to consider the significance of Section 48 (b) employing the expression *"..product obtained directly by that process…"*. The statute in Section 48 (b) constructs a direct and infallible link between the product and the process. Of eminent significance is the usage of the word *"directly"*. All of the above, is an unambiguous manifestation of the intent of the Legislature to confine Section 48 (b) to an inventive process and products directly obtained from that process. It would thus be wholly incorrect to attempt to place product-by-process claims in clause (b) of Section 48 and deprive and

denude inventive products of the protection that the legislation otherwise accords.

164. It would also be pertinent to deal with the findings as rendered by the learned Single Judge and which appear in para 71 of the impugned judgment. The same is reproduced hereinbelow:-

> "**71.** As rightly contended by the Defendants, there is an admission by Vifor that use of iron carbohydrate complexes is known and a water soluble iron (III) hydroxide sucrose complex is a frequently and successfully used preparation. It is stated that the problem to be solved by the present invention is to provide an iron preparation which is especially to be applied parenterally and can be easily sterilized as the known parenterally applicable preparations on the basis of sucrose and dextran were only stable at temperatures up to 100oC, which made sterilization difficult. It is categorically asseverated in the complete specification that present invention is a process for producing iron carbohydrate complexes wherein one or more 'maltodextrins' are oxidized in an aqueous solution at an alkaline 'pH' using 'aqueous hypochlorite solution' and further that when one maltodextrin is applied, the DE value is between 5 and 20 and when mixture of several maltodextrin is applied, the DE value of the mixture lies between 5 and 20 and the DE value of each individual maltodextrin contained in the mixture lies between 2 and 40. Given the admission of Vifor in the complete specification that iron carbohydrate complexes were already known, the only prima facie conclusion that this Court can reach is that the purported invention resides in preparing iron carbohydrate complexes with maltodextrin as the starting material and/orthe step of oxidation using the specified oxidizing agent i.e. aqueous hypochlorite solution. In fact, what Vifor overlooks in making the submission that the process is inconsequential, is that the characteristic properties that it claims in FCM, distinguished from the prior art, are a direct result of the process used by Vifor, an admission that it makes during the prosecution of the patent application and is glaringly evident in the complete specification. Therefore, the scope of Claim 1 of IN'536 is limited to a product obtained through a specific process feature identified therein and cannot cover any and all processes that may be used by a third party to produce FCM and it is thus held that Claim 1 is a product-by-process claim and not a pure product claim."

165. As would be evident from the above, the learned Single Judge essentially holds that iron carbohydrate complexes and a water soluble iron (III) hydroxide sucrose solution were known in the prior art and a successfully used preparation. It is on the basis of the aforesaid that the learned Single Judge at one place observes that the invention lay and resided in the process. The learned Judge further observed that *the "characteristic properties"* that the appellant claims in FCM is a result of the process adopted by it. The view so expressed would have been tenable provided FCM as a compound was known in the prior art. The view taken and noticed above is then summarised with the learned Judge holding that IN'536 is **"…limited to a <u>product obtained through</u> a specific process…"**.

166. This conclusion again fails to meet the contention of the appellant that FCM was a novel composition and compound unknown in the prior art and which fact was neither questioned nor assailed by the respondents. The conclusion appearing in para 71 also ignores the language forming part of claim 1 and which spoke of a product "obtainable by". One could have understood the learned Judge having come to conclude that IN'536 was a pure process claim. However, once it was accepted that it was a product-by-process claim, the findings and conclusions ultimately rendered would not sustain. In our considered opinion, once IN'536 was recognised and accepted to be a product-by-process claim, the question of infringement was necessarily liable to be answered on the basis of product attributes and *de hors* the process of manufacture.

167. We are thus of the firm opinion that the learned Judge clearly erred in appreciating the scope of product-by-process claims and manifestly erred in propounding the theory of distinct principles being

applicable to infringement actions. We for reasons aforenoted have found ourselves unable to accept the line postulated by the majority in *Abbott Laboratories*. We consequently declare that product-by-process claims would have to be examined bearing in mind the propositions enunciated hereinabove.

168. We are also of the considered view that the rule of necessity as articulated in different jurisdictions and noticed hereinabove must guide the acceptance of such claims. It would thus be factors of inability, of structures being indefinable at the time of patent filing and where an applicant is constrained to resort to process terms in order to render sufficient clarity on the inventive qualities of the claimed product which would define and regulate the grant. This would, in our opinion, not only incentivise novel and inventive product acceptance but would adequately balance the needs and imperatives of public interest impacted by the grant of a patent.

J. SUBSIDARY ISSUES

169. That takes us to consider the submissions which appear to have been addressed in the context of DE value and substituted oxidising agents. In our considered opinion, those were aspects pertaining to the manufacturing process of FCM. Once we accept that the inventive attribute of the patent was the chemical compound titled FCM, a modulated process would still be infringing as long as the end product was the same. As was noticed by us hereinabove, the various decisions cited before the learned Judge had themselves recognised the existence of a novel product constituting the heart of a product-by-process claim. The appellants have placed on the record copious material to establish that the respondents were claiming FCM albeit manufactured by deployment of a process different from that of the appellant or with the

use of different oxidising agents. The learned Judge clearly fell in error in basing her conclusion appearing in para 71 as IN'536 being limited to a product obtained through a specific process feature. The learned Judge then proceeded further to hold that claim 1 was a product-by-process claim and not a *"pure product claim"*. The aforesaid findings are clearly contradictory and untenable.

170. One cannot lose sight of the problems in the prior art which FCM sought to overcome. These are evident from the claims and the specifications and which explained the improvements and advantages that FCM had achieved over the prior art. The fact that FCM as a compound was novel and unknown does not appear to have been questioned before the learned Judge. The position remained the same even in the appeal except and to the limited extent of the stand which was taken by Corona and which we shall deal with separately. Other than Corona, none of the other respondents questioned the validity of the patent grant or the novelty of FCM. The record would bear out that while grounds of invalidity have been raised in the suit proceedings, they do not appear to have been raised at this stage. The impugned judgment essentially proceeds on an incorrect appreciation of the principles that must govern product-by-process claims. It then proceeds on the basis that FCM though a product-by-process claim, its scope must be confined since it adopted process terms. At the same time the learned Judge then observes that oxidising agents and iron carbohydrates formed the crux of the invention. These findings are clearly self-contradictory and cannot coalesce. Corona asserted that its product was different and distinct from FCM. Since this was not the basis on which the matter appears to have proceeded before the learned Single Judge, we desist from rendering our opinion on those

contentions bearing in mind the fact that the suits are still pending and it would thus be open for the defendants including Corona to address submissions touching upon the validity of the patent.

171. While on processes and their impact on patentability we deem it apposite to briefly refer to the decision of the Court of Appeal in **Generics (UK) Ltd. and others v. H. Lundbeck A/S**[37]**.***Generics* was a decision concerned with a process of separating the (+) and the (-) enantiomers of citalopram. The dispute which arose was with respect to a product claim for the (+) enantiomer. While dealing with the contours of a product claim, the Court of Appeals decision carries the following significant observations:-

> **"[36]** The judge said that in holding claim 1 insufficient, he was applying this principle. But then he treated the relevant 'technical contribution to the art' as being the inventive step, namely a way of making the enantiomer. That, I respectfully consider, was a mistake. When a product claim satisfies the requirements of s 1 of the 1977 Act, the technical contribution to the art is the product and not the process by which it was made, even if that process was the only inventive step.
>
> **[37]** That proposition is in my opinion established by a number of decisions in the European Patent Office. In *Kawasaki Steel Corporation* (Decision T 0595/90) [1994] OJ EPO 695 claim 1 was to a product, namely a certain description of high grade steel sheeting. In opposition proceedings, the Board of Appeal found that the claimed product 'only has properties which were fully predicted and envisaged. ie the matter is obvious as such'. However, the Board went on, 'this desideratum was not yet actually achieved' and was 'hardly realisable on a commercial scale'. If the patentee had found a non-obvious way of making the product, he was entitled to a product claim, with the full monopoly of the product which that conferred:
>
> > 'It is the view of the Board that a product which can be envisaged as such with all its characteristics determining its identity together with its properties in use, ie an otherwise obvious entity, may become nevertheless non-obvious and claimable *as such* if there is no known way

[37][2008] EWCA Civ 311

> or applicable (analogy) method in the art to make it and the claimed methods for its preparation are therefore the first to achieve this in an inventive manner. (My emphasis).'

[38] This passage has been cited and applied in a number of subsequent cases: see, for example, the decision of the Technical Board of Appeal from opposition proceedings in *EI Du Pont* (Decision T 0233/93) (28 October 1996):

> 'The patent in suit does not deny … that the combination of properties defining the claimed products had been a desideratum which the skilled community had striven to achieve. These properties, however, had been considered to be irreconcilable. According to the [jurisprudence] of the Boards of Appeal [citation of *Kawasaki Steel*] such a desired product, which may appear obvious per se, may be considered non-obvious and claimable as such, if there is no known method in the art to make it and the claimed methods for its preparation are the first to produce it and so do in an inventive manner."

172. Proceeding further to explain the scope of product claims, the Court held :-

> **"[43]** Product claims have had a chequered history. Under the Statute of Monopolies 1623 a patent could be granted only for a 'manner of new manufactures'. By the end of the nineteenth century it was a matter of some controversy whether a new material could be claimed: compare Lord Davey in *Acetylene Illuminating Co v United Alkali Co* (1905) 22 RPC 145 at 153 with Lord Shaw in *British Thomson-Houston Co Ltd v British Insulated and Helsby Cables Ltd* (1925) 42 RPC 180 at 207. It would appear that some chemical product claims were granted, because in 1916 the Comptroller- General of Patents, Mr W Temple Franks, who was a member of a committee chaired by Lord Parker of Waddington appointed to advise on amendments to the Patents and Designs Act 1907, commented unfavourably upon them. In the course of a memorandum 'on German use of our Patent Law', in which he elaborated on the way the Germans 'have carefully studied and most astutely used every provision of our Patent and Trade Mark Laws for the furtherance of their trade', he made these observations:
>
> > 'Another point to be noticed in connection with the use made by the Germans of our patent procedure is their use of what are called "product claims". These claims are claims to any new product per se irrespective of the process by which it is made and are in the form e.g. "as a

> new product the dyestuffs made as above or by any other process". The consequence of such claims especially in chemical manufacture is that the inventor of a process producing a new chemical product is enabled to attack as infringements products produced not only by the process discovered by him but by any other method. These are, in my opinion, in the majority of instances, obstructive and injurious claims, and they very largely aid the establishment of a monopoly in the case of chemical manufacture as they prevent research and invention on analogous lines by other persons.'

173. When the matter reached the House of Lords, Lord Walker explained the concept of product and product-by-process claims in the following words:-

> **"[24]** A 'product-by-process' claim is a claim to a product, but described in such a way as to define it by the process by which it is produced. Such claims are discouraged by the European Patent Office ('EPO'). They are permitted by the EPO only where there is a claim to a new substance whose difference from a known substance cannot be described in chemical or physical terms(see the *Kirin-Amgen* case [2005] 1 All ER 667 at [88]–[91], and also at [109];note that erythropoietin itself could not have been patented because it was a known substance occurring in nature). The expression 'product-by-process' was used in argument in the *Biogen* case ([1997] RPC 1 at 27) and this submission was accepted, if not in those precise terms, by Lord Hoffmann in his opinion in the paragraph ((1996) 38 BMLR 149 at 161, [1997] RPC 1 at40) which is quoted in [26], below. Lord Hoffmann also used it, in relation to the *Biogen* case, in his judgment in the Court of Appeal (at [33])."

174. Lord Neuberger in his speech explained the legal position as follows:-

> **"[69]** The distinction between product claims and process claims, which is, as Lord Walker says, at the heart of this appeal, is effectively taken for granted in the 1977 Act, but it is implicit in s 60 which is concerned with infringement. It specifically refers to cases 'where the invention is a product' and to cases 'where the invention is a process'. As one would expect the same concepts are referred to in the EPC: see arts 52–57 and 167.
>
> **70]** Section 1(1) of the 1977 Act (reflecting art 52 of the EPC) provides that a 'patent may be granted only' if the invention it claims satisfies four requirements. Those requirements are that it '(a) … is new', '(b) … involves an inventive step', '(c) … is

> capable of industrial application', and '(d) … is not excluded by subsections (2) and (3) …' There has never been any suggestion by the appellants that paras (c) or (d) apply in this case; and they no longer seek to rely on paras (a) and (b), now that Kitchin J has concluded that, as at June 1988, escitalopram was both new and inventive (the anti thesis of obvious), and the Court of Appeal has upheld those conclusions.
>
> **[87]** In that connection, the approach of the Board has been consistently along the same lines as that of the Court of Appeal in this case. Thus, in *Kawasaki Steel Corp* Decision T 0595/90 [1994] OJ EPO 695 at 703, the Board said:
>
> > '[A] product which can be envisaged as such with all characteristics determining its identity together with its properties in use, i.e. an otherwise obvious entity, may become nevertheless non-obvious and claimable as such, if there is no known way or applicable (analogy) method in the art to make it and the claimed methods for its preparation are therefore the first to achieve this in an inventive manner.'
>
> (See also the decisions cited by Lord Hoffmann (2008) 101 BMLR 52 at [38],[39].

The English courts thus upheld a product patent on the basis of a method of preparation and which was the first to achieve it an inventive manner.

175. Insofar as the question of allocation of an INN to chemical formulation is concerned, we only observe that the question of patentability is to be examined and evaluated independently. The conferral of an INN cannot be accepted as constituting irrefutable evidence of an invention. It could at best be viewed as corroborative of an assertion of a patentable product having been obtained. However and since we have already examined the issue on a more fundamental plane, there would appear to be no necessity to render any further observation in this respect. Having already examined the issue on merits, we also desist from considering the submissions which were addressed by the appellants based on the opinion of the expert.

176. While closing, we further observe that the finding recorded by the learned Judge on the issue of prosecution history estoppel is based on an apparent misreading of the opposition that was filed before the IPO. As we read that opposition which appears at page 1118 of our record we find ourselves unable to construe it to be an admission of IN'536 being a process claim. In fact and to the contrary, the opposition asserts that the suit patent relates to FCM. It proceeds to aver that it *"...also relates to a process of preparation of ferric carboxymaltose".* The aforesaid opposition thus appears to be consistent with the stand taken by the appellant in the suit.

177. As was noted by us hereinbefore, the respondents had also argued that the appellant was rightly denied relief since it had failed to follow the route of filing divisional applications and thus reinforce its case of the patent relating to a product. According to them, nothing restricted the appellant from following that procedure before the IPO and thus acting in conformity with the steps that it had taken before the EPO and the USPTO. We find ourselves unable to countenance this contention bearing in mind the indubitable fact that the suit patent came to be granted on 25 June 2008. The decision in *Abbott* came to be pronounced only thereafter and more particularly on 18 May 2009. It is this decision which appears to have prompted the filing of the divisional applications. The principles propounded by Abbott had not been reiterated in India prior to the passing of the impugned order. In any case and as is evident from the decision handed down by the EPO on 14 September 2016, it had categorically found that the original application itself claimed a novel product. It had pertinently observed that the process for production of the complex is not substantial for the invention. It consequently held that deletion of a process feature and its

substitution by two product features does not violate the applicable guidelines.

178. Both Mr. Lal as well as Mr. Natraj had vehemently contended that infringement is concerned with a claim and not a product. According to them, while trying an infringement allegation, courts do not undertake a comparison between two rival products but focus their attention on the claims. They had submitted that it is this principle which constitutes the logic for process terms being viewed as limiting. We find ourselves unable to accept this contention for the following reasons.

179. Undoubtedly, courts would construe and interpret claims as opposed to comparing two rival products while evaluating an allegation of infringement. Our explanation of product-by-process claims in the preceding parts of this decision is not founded on an understanding of claims being either ignored or relegated to a secondary position while interpreting such patents. What we have fundamentally come to conclude is that product-by-process claims primarily pertain to a product although the claim may have chosen to describe the invention with the aid of process terms. In fact the learned Judge herself held that FCM was a product-by-process claim. What we have essentially held is that the product attribute of such a patent cannot be effaced or ignored merely because the question stands raised in an infringement action. What we have been unable to countenance are two sets of standards being employed depending upon whether it be the stage of grant or infringement analysis. This since claims remain unvarying and constant. The principle that we have enunciated clearly does not result in a comparison between products nor was such a precept propounded.

K. EPILOGUE

180. In our considered opinion, the fundamental fallacy in the judgment flows from the learned Judge's understanding of a distinction between a *"product by process claim"* and a *"pure product claim"*, an aspect which is alluded to in para 71. It is this foundational and conceptual mistake which renders the impugned judgment unsustainable. The learned Judge has fundamentally erred in understanding product-by-process claims as "*limited to a product obtained through a specific process feature"*. The aforesaid view fails to correctly appreciate the well settled principle of product-by-process terms being an established and recognised mode of drafting claims and such a method being adopted in cases where products resist definition except by resort to process terms. The view taken is rendered further untenable since it appears to have been the uncontested position before the learned Judge that FCM was not known in the prior art. This since although invalidity was pleaded, the respondents chose not to press that ground at the stage of consideration of the interim injunction applications.

181. While closing our discussion on the subject of product-by-process, we also deem it apposite to broadly enunciate the circumstances when such claims may be entertained. This since there is an imperative necessity to balance the interest of the inventor and at the same time securing public interest and thus ensuring that the claim does not travel beyond the invention itself. As has been noticed hereinabove, the IPO guidelines accept product-by-process claims principally. They also postulate that such claims would only be entertained when the applicant is able to establish that a novel product unknown in the prior art has come to be invented. Those guidelines in unequivocal terms

provide that a novel process would not justify the entertainment of a product-by-process claim. They thus and in our opinion correctly lay emphasis on novelty and inventive attributes of a product as a sine qua non for such claims being accepted. Bearing in mind the position which emerges upon a consideration of the guidelines framed by the EPO as well as the USPTO, we would deem it appropriate to hold that such claims once entertained must be informed by the rule of necessity and it being impracticable to fully describe the inventive attributes and characteristics of the invention except by resort to process terms. We would be of the opinion that such claims would merit acceptance where the product is indefinable except when explained alongside a process of manufacture. It would thus be factors of inability, of structures being indefinable at the time of patent filing and where an applicant is constrained to resort to process terms in order to render sufficient clarity on the inventive qualities of the claimed product which would define and regulate the grant. This would, in our opinion, not only incentivise novel and inventive product acceptance but would adequately balance the needs and imperatives of public interest impacted by the grant of a patent.

182. We had in the preceding parts of this judgment noted the contention of Mr. Natraj who had commended for our consideration the rule of deference as propounded in *Wander* and of appellate courts interfering only in cases of manifest or patent mistakes. We are of the firm opinion that the legal position as enunciated by the learned Judge suffers from patent and manifest illegalities as explained in the body of this decision and thus clearly warranting interference in appeal.

L. CARDINAL PRINCIPLES

183. We would thus record our conclusions in the following terms:-

A. A product-by-process claim is an amalgam which "straddles" the otherwise recognised distinction between products and process patents *per se*. A product-by-process patent is founded on a claim relating to a novel product whose unique attributes are sought to be explained by reference to its manufacturing process. These patents owe their genesis to cases where new products could not be fully described by their structure compelling the patent applicant to rely upon and refer to the process features.

B. It would be wholly incorrect to hold that products must necessarily and invariably be described by their composition and structure or at least recognise it to be an inflexible precept. That would go against the underlying compulsions which govern product-by-process claims. Patent Registries and courts globally acknowledge and accept the possibility of structurally indefinable products and have propounded the "rule of necessity" with respect to product-by-process claims. As understood by the IPO Guidelines, product-by-process patents are neither unconventional nor unknown and the Indian patent regime itself contemplates product-by-process claims.

C. Product-by-process claims are foundationally referable to a novel or unobvious product and the patentability of that product not being dependent upon the mere novelty of the process adopted. A product is not rendered novel merely by virtue of the fact that it is produced by a new process, because if novelty is claimed only in respect of a process, it would be treated and granted as a process patent.

D. One principle which finds resonance across jurisdictions and stands embodied even in the guidelines framed by the IPO, EPO and the USPTO is that a product-by-process claim would be accepted and accorded statutory protection, only if the product itself be novel.

Irrespective of the language in which such a claim may be couched, it is necessary that such a patent application speak of a novel product. It is this foundational precept on which product-by-process claims are tested.

E. The guidelines as well as the judgments rendered in the context of product-by-process claims speak in unison when they state that for assessing novelty one must disregard the process terms and discern whether the product possesses novelty. We are reminded that a product is not rendered novel merely by virtue of the fact that it is produced by a new process.

F. The statute confers a right upon the patentee to restrain the making or using of a product or a process. However, and as was observed in *Hospira UK Limited*, the dichotomy between a product and a process is not liable to be viewed as operating in a water tight compartment. *Hospira UK Limited* eloquently explains the *raison de' etre* for the acceptance of product-by-process claims as being founded on the needed imperative of striking a balance between *"clarity and fairness"* and according a limited leeway in that *"limited class of cases"* where the patentee is unable to identify a characteristic or parameter disclosed in the patent except by way of an *"obtainable by"* process definition. It thus formulates the tests to be borne in mind while evaluating such a claim to be whether a characteristic or attribute is discernible from claims structured in product-by-process terms. Viewed in that light, it is manifest that the decision propounds a reasoned, just and balanced threshold for examination of product-by-process claims.

G. The contention that process features serve as a limitation during infringement proceeds on the incorrect and untenable premise that notwithstanding the product being novel, it must be presumed that the

patentee sought and claimed protection only over the process and thus the same acting as a limitation. More fundamentally, such an interpretation ignores the undisputed fact that such a claim may in fact have been recognised at the stage of grant as a novel product.

H. Product-by-process claims pertain to a product which is novel and inventive and unknown in the prior art. It would thus remain a product which would fall within the ambit of Section of 48(a). The difficulty in discerning the scope of such claims would not constitute a valid basis to deprive a true invention of the protection which the Act confers. It would be incorrect to rule that product-by-process claims must be inevitably curtailed by process terms.

I. Product-by-process claims, although employing process terms, are fundamentally concerned with an inventive product and the reference to a process being only to aid in explaining the novel attributes of a new product unknown in the prior art. Thus, it would be unjust and incorrect to prune down a claim pertaining to such a patent as being confined to merely a process. That would clearly be doing violence to well established tenets of claim construction. According such an interpretation firstly proceeds on the premise that notwithstanding the product being novel, it must be presumed that the patentee sought and claimed protection only over the process and thus the same acting as a limitation. More fundamentally, that interpretation commands us to ignore the undisputed fact that such a claim may in fact have been recognised at the stage of grant as a novel product.

J. The primary concern of the Act is an invention as is evident from Section 2(1)(j) of the Act and which may relate not just to a new product but even a process both of which may involve an inventive step. We fail to discern any logic in recognizing distinct tests of novelty

being applicable at the stage of patentability and those that may be relevant for deciding a question of infringement. It is pertinent to observe that both at the stage of grant as well as while considering an allegation of infringement the terms and the language of the claim remain unaltered. Claims and specifications do not change hues but remains static. We thus principally find ourselves unable to countenance the submission that separate or distinct tests of novelty should apply between the grant of a patent and the examination of an allegation of infringement.

K. Since the terms and the language of the claim remain unaltered and consistent both at the stage of grant as well as while considering an allegation of infringement, separate or distinct tests of novelty should not apply between the grant of a patent and the evaluation of an infringement allegation. As long as a product-by-process claim pertains to a product, which is novel and has no parallel in the prior art, the mere fact that the patentee chooses to describe the invention more exhaustively by reference to process terms, and in light of the difficulties of expression alluded to above, the tests should in our opinion remain unchanged.

L. There is no justification to hold or recognise the law to be that while an inventive characteristic of a product sets it apart from the prior art, the same should be disregarded when it comes to infringement analysis. Acceptance of the proposition that the patentability and novelty of a product becoming triable based upon two separate and distinct set of rules would invariably result in the creation of an incongruous and anomalous situation. It would essentially lead to a position where while the patent may validly be accepted to be a product at the stage of grant, it becomes confined to a process for the purposes

of examining infringement. This would clearly amount to propagating a double standard approach and which would be unjust and untenable.

M. Sections 107 and 64 constitute an added ground which convinces us to reject this contention. If grounds of revocation which constitute a foundational ground impacting the validity of the grant itself be a ground which can be validly urged as a defence in an infringement action, there exists no justification to countenance a different set of rules being employed.

N. Turning back to our statute, it becomes pertinent to observe that Section 48(b) on its plain language is concerned with a process patent per se. It is with the aforesaid objective that the Act proceeds to create a statutory bar and prevents third parties from either using the patented process or employing the same for the purposes of manufacture of a product which could be said to have been directly obtained from that process. Section 48(b), however, does not adopt the *"obtainable by"* language while referring to a process claim.

O. A process claim and the extent of protection that can be claimed in respect thereof would have to draw colour and content from Section 48(b) and which embodies the phrase *"obtained directly by that process"*. We would thus draw and acknowledge the existence of a distinction between *"obtained by"* and *"obtainable by"* language embodied in the claim. The words *"obtainable by"* would appear to convey a descriptive process by which the claimed product could be manufactured or produced. However, that process in itself need not and invariably be the inventive element of the patent.

P. The expression *"obtained by"* on the other hand would be intended to convey a direct linkage between the product and the process. However, in the context of our statute, the latter would in most

situations be concerned with a process claim referable to Section 48(b) and ultimately liable to be construed accordingly be it for patentability or infringement analysis. Consequently, an *"obtained by"* claim tested whether on the anvil of Section 48(b) or the canons of claim construction would lead us to the same conclusion, namely, the patentee having intended to restrict the scope of the claim to the recited process. This would also follow when examined from the eye of the notional audience.

Q. Section 48(b), however, does not adopt "obtainable by" language while referring to a process claim. The words "obtainable by" convey a descriptive process by which the claimed product could be manufactured or produced. The usage of "obtainable by" language is identical to what occurs in Section 48(a) of our Act and extends to products claims per se.

R. Ultimately, a product-by-process claim would have to meet the test of pertaining to a novel and inventive product as opposed to a process. It will thus be wholly incorrect to abridge or truncate a product-by-process claim to fall within the ambit of Section 48(b). In our considered opinion as long as the product-by-process claim pertains to a product which is novel and inventive and unknown in the prior art it would remain a product which would fall within the ambit of Section of 48(a).

S. Consequently, courts when faced with such claims would have to discern from the language of the claim and the specifications whether the claim pertains to an inventive product or merely a novel process. The difficulty in discerning the scope of such claims would not constitute a valid basis to deprive a true invention of the protective cover which the Act confers. In any event, it would be wholly incorrect

and unjust to postulate a rule that product-by-process claims must be inevitably curtailed by process terms.

T. *Hospira UK Limited* was principally dealing with an "obtained by" claim. It also recognised *Kirin Amgen* as being an authority for the proposition that infringement of "obtained by" claims would be answered in the affirmative only if it were found that the infringing product had actually been made *"by the relevant process"*. Hence, on merits, since *Hospira UK Limited* related to an *"obtained by"* claim, it would clearly fall within the scope of Section 48(b**)** of our Act.

U. Further, a holistic reading of *Hospira UK Limited* shows that the said decision cannot be recognized to be an authority for the proposition that the principles of claim construction which may apply while answering a question of patentability would not be relevant in actions for infringement. Whether the product-by-process claim relates to or does not relate to an inventive product and is confined to a novel process, would essentially turn upon the facts of each case. Only where the claim is discerned and found to be confined to a novel process would we be justified in recognising the claim as falling squarely within the ambit of Section 48(b) of the Act.

V. The position which has been taken by the majority in *Abbott Laboratories*¸ i.e., process features serving to limit the product-by-process claim, was a departure from a host of precedents (*Scripps* and *SmithKline*) and also does not appear to have found acceptance in any other jurisdiction. Even the Japanese Supreme Court in *2012 (Ju) 1204, Minshu Vol.69 No.4* did not accept that process terms are limiting or that they remove the focus from the inventive product itself and rejected the *"double standard"* approach with respect to tests for patentability and infringement.

W. There is an imperative necessity to assess novelty and the scope of the patent right based on a consistent and unchanging criterion. The acceptance of the argument canvassed by the respondents would compel us to recognise the examination process being subject to a set of rules distinct and contrary to the principles which would apply to infringement analysis. The patentability and novelty of a product thus becomes triable based upon to two separate and distinct set of rules.

X. We thus find ourselves unable to concur with the *Abbot* rule of process terms limiting the scope of protection that can be claimed in an infringement action. There cannot be shifting lines of protection-one which would imbue the examination process and another completely distinct and discordant test for infringement. If the product is discernible, unobvious and novel, it cannot be ignored in the course of trying an infringement action.

Y. The submissions based on *Abbott Laboratories* proceed on the premise that a product-by-process claim would render the notional audience incapable of discerning the true intent of the patentee. That, however, is a question which relates to claim construction. The aforenoted submission also fails to bear in consideration that the onus of proving infringement lies on the patentee. It would thus be incumbent upon the patent holder to establish that what was claimed was in fact a product and the claims read together with the specifications lead us unerringly towards that conclusion. In any case, the apprehended confusion or lack of clarity would not justify accepting the principle that for the purposes of evaluating an allegation of infringement one must necessarily proceed on the basis that process terms limit or deprive product-by-process claims of their essence. We are thus of the firm opinion that the theory of a distinct set of rules

being applicable to infringement actions is wholly incorrect and untenable.

Z. We find that whether it be a question of validity or infringement, the patentability of a product can always be assailed irrespective of the process terms. In fact, if a defense of invalidity were to be raised in a suit for infringement, it would be open for a defendant to assert that the patent has been wrongly granted either on the ground of a lack of novelty or otherwise being unpatentable. This in light of the right unambiguously conferred by Section 107. Such a challenge would itself be addressed upon the product itself. That challenge would not rest upon the process terms at all. It would be incumbent upon such a defendant to prove that the claim does not relate to a novel or inventive product and that assertion would clearly not be influenced by the mere recitation of the process terms.

AA. Therefore, and in our considered opinion, a product-by-process claim would necessarily have to be examined on the anvil of a new and unobvious product irrespective of the applicant having chosen to describe the invention by referring to a process of manufacture. The mere adoption of the product-by-process format would not result in a novel product being downgraded to Section 48(b) of the Act. It would inevitably have to be tested on principles enshrined in Section 48(a). Mere usage of process terms cannot be accepted as limiting nor is there any justifiable rationale to accept the advocated distinction between validity and infringement. If the rule of necessity were to compel the applicant to submit an application embodying a product-by-process claim, there would appear to be no justification to stultify the extent of protection.

BB. The question of patentability is to be examined and evaluated independent of the allocation of an INN to a chemical formulation. Conferral of an INN cannot be accepted as constituting irrefutable evidence of an invention and could at best be viewed as corroborative of an assertion of a patentable product having been obtained.

CC. The fundamental fallacy in the judgment flows from the learned Judge's understanding of a distinction between a *"product by process claim"* and a *"pure product claim"*, an aspect which is alluded to in para 71. It is this foundational and conceptual mistake which renders the impugned judgment unsustainable. The learned Judge has fundamentally erred in understanding product-by-process claims as "*limited to a product obtained through a specific process feature"*. The view taken is rendered further untenable since it appears to have been the uncontested position before the learned Judge that FCM was not known in the prior art.

M. DETERMINATION

184. We accordingly allow the present appeals and set aside the impugned judgment dated 24 July 2023. While an interim injunction would not be warranted at this stage, the suit proceedings may be taken forward bearing in mind the legal position as enunciated above. We also leave it open to the appellants to press their claim for deposit of percentage of sales at the appropriate stage and subject to further orders being passed in the pending suits. All rights and contentions of respective parties in that respect are kept open.

185. Though needless to state we deem it appropriate to clarify that we have only enunciated the legal position with respect to product-by-process claims and why the prima facie reasons assigned in the impugned judgment were rendered unsustainable. Thus all other

objections and defences taken by the respondents are open to be addressed in the pending suits.

YASHWANT VARMA, J.

DHARMESH SHARMA, J.

FEBRUARY 07, 2024
kk/neha