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Manufacturing Patents

A Study on Metformin and Paracetamol Patents in India

TWN
Third World Network

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1 Introduction

Patent evergreening – the practice of obtaining multiple patents on known substances through incremental modifications – represents a significant challenge to public health objectives and the innovation ecosystem in developing countries like India. This phenomenon, also known as secondary patenting or patenting of incremental innovations, occurs when pharmaceutical companies seek to extend the patent monopoly on known medicines/substances by claiming patents on minor formulation changes, dosage variations or new combinations. Such practice effectively extends the market monopoly beyond the original patent term of 20 years. The Indian Patents Act, 1970 incorporates robust safeguards against this practice, most notably Section 3(d), which prohibits patenting of new forms of known substances unless they demonstrate enhanced efficacy, and Section 3(e), which bars patents on mere admixtures of known components lacking synergistic effects.

Despite these legislative protections, empirical evidence reveals widespread disregard for these safeguards in pharmaceutical patent grants. This study investigates wrongful patent grants on two quintessential off-patent molecules: metformin and paracetamol. These medicines represent typical specimens for examination – both have been therapeutically used for over 70 years and are currently listed under India's National List of Essential Medicines (NLEM) 2022. While the patents on their base molecules have long expired and generic production is widespread, the study reveals that 146 product patents have been granted on these two drugs alone, encompassing various formulations, combinations and derivatives.

Through systematic analysis of patents granted between 2005 and 2023 on these two old medicines, combined with detailed case study examinations of patent prosecution histories, this report identifies systematic failures within the Indian Patent Office (IPO) in applying the Patents Act safeguards against evergreening. The research reveals that patents have been granted for trivial modifications, altered tablet dimensions, minor excipient changes and arbitrary fixed-dose combinations without demonstrable enhancement in therapeutic efficacy. These findings raise criti-

cal questions about the IPO's gatekeeping role and accountability. More broadly, this study contributes to the discourse on balancing patent protection with public health imperatives, particularly as India positions itself as "the pharmacy of the developing world" and pursues greater pharmaceutical self-reliance and accessibility to essential medicines.

The second part of the study discusses the safeguards in the Indian Patents Act against evergreening. The third part explains the methodology of the study as well as the limitations of the study. The fourth part provides a brief history of these two medicines. Parts five and six of the study discuss the various details of the wrongful patents such as the applicant's profile, the types of patent claims etc. The seventh part contains detailed analysis of two recent patents granted on metformin and paracetamol. The last part contains the conclusions of the study, including suggestions to avoid the grant of wrongful patents and to improve the accountability of the Patent Office.

2 Safeguards Against Evergreening

The Indian Patents Act contains several provisions to check the granting of multiple patents on the same molecule. Firstly, the Act sets a high threshold level of patentability by defining invention and inventive step. Secondly, Section 3 of the Act carves out 15 categories from the statutory definition of invention, thereby excluding them from patentability. Three subsections under Section 3 – (d), (e) and (i) – are directly aimed at curbing evergreening practices. Of these, Section 3(d) stands out as the most significant subsection. Introduced in 2005, it prohibits the grant of patents on new forms of known substances unless the applicant demonstrates enhanced efficacy. Section 3(d) bars the patenting of "the mere discovery of any new property or new use for a known substance", effectively foreclosing patent protection for new use claims over existing molecules. Section 3(d) reads:

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

Instead of imposing a blanket prohibition on the patenting of known substances, Section 3(d) establishes a case-by-case framework, under which a patent applicant may overcome the exclusion by demonstrating enhanced efficacy of the claimed invention. Thus, the exclusion is not an automatic or ex-ante rejection, but is subject

to each application being examined on its individual merit. Further, there is ambiguity in the use of the word "efficacy". The word has not been defined in the statute and is subject to diverse interpretations including technical efficacy, therapeutic efficacy or some other standard.

The Madras High Court provided significant clarity on the interpretation of the term "efficacy" in *Novartis AG vs Union of India* (2007 4 MLJ 1153, at 13), wherein the Court held that:

> "Going by the meaning for the word 'efficacy' and 'therapeutic' extracted above, what the patent applicant is expected to show is, how effective the new discovery made would be in healing a disease / having a good effect on the body? In other words, the patent applicant is definitely aware as to what is the 'therapeutic effect' of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for. Therefore it is a simple exercise of, though preceded by research, - we state".

The interpretation was further affirmed and cemented by the Supreme Court of India in *Novartis AG vs Union of India & Ors* (2013 13 S.C.R. 148, at 180) (hereinafter the "Novartis judgement"), which conclusively settled the interpretation of Section 3(d). It stated:

> "What is 'efficacy'? Efficacy means 'the ability to produce a desired or intended result'. Hence, the test of efficacy in the context of section 3(d) would be different, depending upon the result the product under consideration is desired or intended to produce. In other words, the test of efficacy would depend upon the function, utility or the purpose of the product under consideration. Therefore, in the case of a medicine that claims to cure a disease, the test of efficacy can only be 'therapeutic efficacy'. The question then arises, what would be the parameter of therapeutic efficacy and what are the advantages and benefits that may be taken into account for determining the enhancement of therapeutic efficacy? With regard to the genesis of section 3(d), and more particularly the circumstances in which section 3(d) was amended to make it even more constrictive than before, we have no doubt that the 'therapeutic efficacy' of a medicine must be judged strictly and narrowly. Our inference that the test of enhanced efficacy in case of chemical substances, especially medicine, should receive a narrow and strict interpretation is based not only on external factors but there are sufficient internal evidence that leads to the same view. It may be noted that the text added to section

> 3(d) by the 2005 amendment lays down the condition of 'enhancement of the known efficacy'. Further, the explanation requires the derivative to 'differ significantly in properties with regard to efficacy'. What is evident, therefore, is that not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, as seen above, is its therapeutic efficacy."

It is thus unequivocally established that a patent claim on a known medicinal substance must demonstrate enhanced therapeutic efficacy to satisfy the requirements of Section 3(d).

During the Parliamentary debate on the Patents (Amendment) Bill on 22 March 2005, the then Minister of Commerce and Industry stated (Lok Sabha, 2005):

> "…In regard to evergreening, I just want to read out section 3(d) which says that a mere discovery [of] a new property or a new use [of] a known substance or the mere use of known process in or new product – these are exceptions, these will not be granted any patent – and substances obtained by a mere ad-mixture resulting only in aggregation of properties of the components thereof or, processes of producing such substances will not be given patents. There is no question of evergreening."

Empirical evidence, however, reveals that the Indian Patent Office has continued to grant patents on known substances at a significant rate. These studies demonstrate that the safeguards against patent evergreening have been applied unevenly and inadequately, leading to the grant of a considerable number of pharmaceutical patents in contravention of the Patents Act. In 2010 a study identified 86 patents granted between 2005–10 for minor modifications of existing pharmaceutical products (James, 2010). Though another study found that Section 3(d) was cited as a ground for rejection in 69% of the cases (Ali et al., 2017), a subsequent study by the same authors, examining 2,293 pharmaceutical patents granted between 2009 and 2016, found that 72% of the granted patents were secondary patents, i.e., patents claimed over an already known substance (Ali et al., 2018). Furthermore, the study found that nearly 78% of the granted patents were inconsistent with Section 3(d), with the granted claims covering formulations, physical variants, salts, esters, ethers, prodrugs, uses, isomers and related modifications.

Similarly, Sampat and Shadlen (2018), analyzing over 2,500 pharmaceutical patent applications, found that while Section 3(d) had contributed to higher rejection rates for secondary patents relative to primary ones, its application remained notably inconsistent. Patent examiners frequently failed to rigorously assess "enhanced efficacy", thereby permitting patents on trivial modifications to proceed. The study

also found a vast majority of secondary patent applications covering new forms, dosages or salts of existing drugs moved through the examination process without being subjected to meaningful scrutiny under Section 3(d).

Taken together, these studies provide compelling evidence that patentability criteria and statutory safeguards such as Section 3(d) have been applied inconsistently by the Patent Office, resulting in patent grants in contravention of the Patents Act.

Section 3(e) of the Patents Act is another critical safeguard against patent evergreening, particularly in respect of combination medicine claims. It excludes from patentability "a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance". Accordingly, a fixed-dose combination of two or more medicines that produces only a combined effect of its individual components is not patentable. The Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals (OCGPDTM, 2014) (hereinafter "Guidelines for Examination") further elaborate: "Claims related to compositions obtained by mere admixture resulting in aggregation of the properties of the individual components are not patentable under section 3(e) of Act. However, in a composition if the functional interaction between the features achieves a combined technical effect which is greater than the sum of the technical effects of the individual features, it indicates that such a composition is more than a mere aggregation of the features."

Thus, a fixed-dose combination can overcome the Section 3(e) barrier only when its pharmacological activity demonstrably exceeds the aggregate pharmacological activity of its individual components – a threshold that may be established through any of the standard pharmacological tests recognized in the field.

Against this backdrop, the present study investigates the wrongful grant of patents on two established medicines – **metformin** (antidiabetic) and **paracetamol** (antipyretic/analgesic), both of which are listed under the National List of Essential Medicines 2022 (Government of India, 2022). These molecules have been in therapeutic use for over 70 years and have long since entered the public domain, enabling widespread generic manufacturing. Yet the study reveals that secondary patents covering formulations, compositions, combinations and derivatives continue to be granted in respect of the molecules – thereby creating multiple monopolies on the same molecule. A central objective of this study is to compile focused empirical evidence on the wrongful grant of patents on well-known medicines, and to evaluate the existing accountability mechanisms within the Indian Patent Office and their effectiveness in preventing such grants.

The study identifies at least 146 product patents granted in relation to these two molecules. Through a systematic examination of these patents, the study identifies instances of wrongful grant, the patent applicant profiles and systemic accountability concerns. This analysis not only critiques the IPO's patent examination practices but also advances recommendations to prioritize patent quality over quantity, ensuring that the patent system remains aligned with public health imperatives.

The proliferation of wrongful patents raises serious questions about the IPO's role in fostering genuine innovation as opposed to entrenching monopolies over existing medicines. As India's patent grant rate stands at approximately 80% of the processed applications – significantly higher than global averages, as per the World Intellectual Property Organization (WIPO)'s 2025 indicators – the focus must shift from the sheer volume of grants to the quality of the patents being granted and genuine inventiveness of the patented products.

3 Methodology (Brief Overview)

In summary, the study was conducted through the following sequential steps:

Database Search and Validation: The study commenced with a systematic search of the proprietary database LexisNexis TotalPatent One, using International Non-proprietary Names (INNs) and common chemical names for metformin and paracetamol, covering patents granted from 2005 to 2023. Preliminary patent lists were verified against the Indian Patent Advanced Search System (InPASS) on the IPO website. Only granted patents with product claims were retained, since process patents were not treated as significant barriers to the entry of generics.

Patent Classification: In the second step, the shortlisted patents were classified by claim type (e.g., pharmaceutical composition, combination, derivative) and by applicant category (e.g., pharmaceutical companies, natural persons, or academic and research institutions). Applicant nationality was also mapped to distinguish domestic filings from foreign ones to assess relative dominance.

Case-Study Analysis: For more detailed qualitative assessment, two recently granted patents were selected as case studies, one relating to metformin and one to paracetamol. The prosecution history for each one was reviewed, including the First Examination Report (FER), applicant responses, hearing notices and written submissions. Objections under key sections of the Patents Act [e.g., Section 2(1)(ja) for inventive step, 3(d) for new forms, 3(e) for admixtures] were critically evaluated against applicant arguments and IPO decisions.

Data Collection: Quantitative data on the number of grants, claim categories and applicant profiles were compiled, and examined for patterns over time, including potential correlations with changes in IPO procedures. The analysis was restricted to product patents granted in India and excluded applications that were refused, expired or abandoned. The full dataset is available in Annex 1.

Since the study covers patents granted between 2005 and 2023, the absolute number of patents granted on metformin and paracetamol may differ from current figures; however, the directional trends identified in the study remain robust and policy-relevant.

4 A Brief History of Metformin and Paracetamol

Metformin: Metformin is one of the oldest antidiabetic medicines and remains the cornerstone of treatment for type 2 diabetes globally. It belongs to the class biguanide and acts primarily by reducing hepatic glucose production and improving peripheral insulin sensitivity. *Galega officinalis*, a guanidine-containing plant, has been used in traditional medicine to treat diabetes-like symptoms since the Middle Ages. Metformin was first synthesized in the 1920s and clinically investigated in the 1940s–50s, with broader adoption as a first-line therapy from 1958 onwards in the United Kingdom and other European countries (Bailey, 2017). Patent protection on the base metformin molecule has long expired in all major jurisdictions. Metformin was approved by the US Food and Drug Administration (FDA) in 1994 for the treatment of type 2 diabetes (Bailey, 2017). Today, metformin is globally off-patent, widely available in hundreds of low-cost generic versions, and is listed in the World Health Organization (WHO)'s Model List of Essential Medicines (WHO, 2025) and India's National List of Essential Medicines (Government of India, 2022). It is marketed in many forms including immediate-release tablets, extended-release formulations, fixed-dose combinations with sulfonyl urea (glimepiride), DPPIV inhibitors, SGLT2 inhibitors and others. Given its age and the expiry of any primary patents, new patents should in principle be confined to genuinely innovative dosage forms or combinations that demonstrate clear therapeutic superiority. Yet this study identifies a dense thicket of metformin-related product patents in India, raising questions about the nature and quality of the claimed inventions.

Paracetamol: Paracetamol, alternatively known as acetaminophen, carries one of the longest clinical histories. It is amongst the most widely used antipyretic and analgesic drugs worldwide. First synthesized in the late 19th century, it entered the US market in 1950 and achieved widespread clinical use in the mid-20th century as a safer alternative to aspirin in specific groups of patients (Prescott, 2000). The UK patent expired in 1963, and the US patent lapsed earlier, leading to extensive generic competition by the 1970s. Like metformin, the base paracetamol molecule has been off-patent for more than six decades and is now ubiquitously available.

In India, paracetamol is heavily generalized, features in the NLEM as an essential medicine and is supplied by multiple generics at very low prices of around ₹0.80–₹1.20 per tablet. It is marketed in a wide range of dosage forms including tablets, syrups, paediatric formulations, suppositories and numerous fixed-dose combinations with anti-cold agents, antihistamines and in some opioids.

Both metformin and paracetamol therefore represent classic examples of long-off-patent molecules where the base compound is in the public domain, with access largely secured through robust generic competition. Any new product patents built around these molecules raise immediate questions about the rigour of the Patent Office's assessment of inventive step and about the consistent application of India's evergreening safeguards under Section 3(d) and 3(e) of the Patents Act.

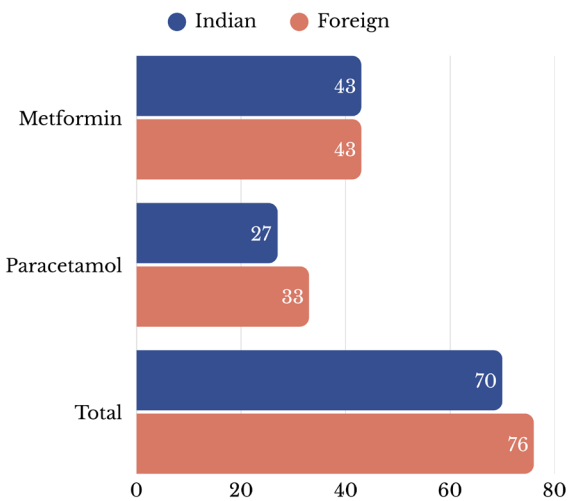
5 Overview of Patenting on Metformin and Paracetamol

Despite both being very old drugs, the number of product patents granted for metformin and paracetamol is substantial. The study identified a total of 146 granted product patents – 86 patents covering metformin and 60 patents covering paracetamol. Out of these 146 patents, 65 claimed the medicine in claim 1 (independent claim), whereas the remaining 81 patents claimed the medicine in other claims (dependent claims, other than claim 1).

Indian vs. Foreign Applicants

While the majority of the patentees are foreign applicants (76, or 52.1% of the total), Indian patentees account for 70 patents (47.9%). For metformin, Indian and foreign applicants hold the same number of patents each, i.e., 43. For paracetamol, Indian applicants hold fewer patents (27, or 45%) than foreign applicants (33, or 55%).

Figure 1: Indian vs. Foreign Patent Applicants



Breakdown by Applicant Type

The applicants are categorized across five types: pharmaceutical companies account for the largest share at 76.03% (111 out of 146 patents), followed by natural persons at 18.49% (27 patents), educational institutes at 4.11% (6 patents), and one patent each held by not-for-profit agencies and research institutes (0.68% each).

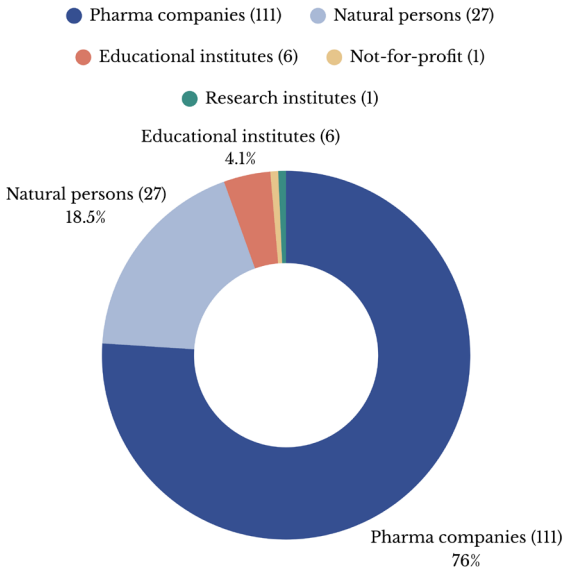
- Pharmaceutical companies
  Of the 111 patents held by pharmaceutical companies, 69 relate to metformin and 42 to paracetamol. Indian companies lead with 46 (41.44%), followed by the US with 18 (16.22%), France with 11 (9.91%), and Germany and the UK with 8 patents each (7.21% each).

- Natural persons
  Natural persons hold 27 patents – 12 for metformin and 15 for paracetamol. Indian natural persons dominate both categories, holding 8 of the 12 metformin patents and 12 of the 15 paracetamol patents.

- Educational institutes
  Educational institutes hold 6 patents – 4 for metformin and 2 for paracetamol. Indian institutions again lead, holding 3 of the 4 metformin patents and 1 of the 2 paracetamol patents.

- Others
  The remaining two patents are held by a not-for-profit agency (1 patent, metformin) and a research institute (1 patent, paracetamol).

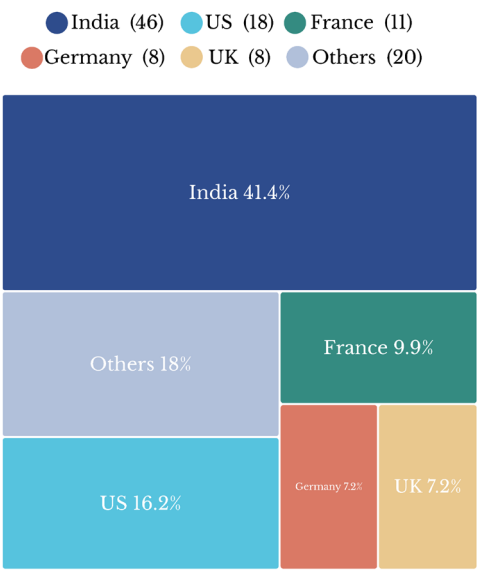
Figure 2: Number of Patents Granted, By Entity



Nationality Breakdown of Pharma Companies

As illustrated in Figure 3, Indian pharmaceutical companies hold the largest share – 46 patents out of the total 111 patents owned by pharmaceutical companies – followed by the United States, France, Germany and the UK.

Figure 3: Nationality Breakdown of Pharma Companies



6 Claim Coverage: What Is Being Patented

The 146 patents analyzed cluster into two broad sets – single-category patents and mixed-category patents – with pharmaceutical combinations and compositions dominating the landscape.

Pharmaceutical Compositions (43.15% – 63/146)
Pharmaceutical compositions constitute the largest category. These are formulated as mixtures of one active pharmaceutical ingredient (API) and excipients designed to deliver a safe, stable and effective medication. Claims in this category include a wide range of dosage forms, including immediate-release, sustained-release, bilayer and multi-layer tablets, injectable formulations, infusions, and specialized paediatric and geriatric formulations. For paracetamol, the majority of patents are for compositions (36/60, or 60%), e.g., paediatric formulations, microemulsions and stability-enhanced products.

Pharmaceutical Combinations or Fixed-Dose Combinations (FDCs) (42.47% – 62/146)
Fixed-dose combinations – formulations containing two or more APIs in a single dosage form – constitute the second largest category. FDC claims in this study combine metformin or paracetamol with one or more other APIs across similar dosage form technologies including immediate-release, sustained-release, bilayer and multi-layer tablets, injectable formulations, infusions, and specialized paediatric and geriatric formulations. For metformin, the patenting swerves towards combinations (43/86, or 50%), especially FDCs with other antidiabetics, reflecting the drug's central role in multi-drug diabetes regimens. Paracetamol FDC patents (19/60, or 31.67%) predominantly combine it with anti-cold or analgesic agents.

Derivatives (1.37% – 2/146)
Derivative patents cover structural modifications of metformin or paracetamol – including salts, esters and prodrugs – which represent a minimal but notable category.

Mixed-Category Patents (13.01% – 19/146)
Mixed-category patents are complex, umbrella-type patents that combine different types of claims in a single patent (Table 1).

Table 1: Mixed-Category Patents

Category	Patents	Share
New compound + metformin as its salt	7/146	4.79%
Composition + combination claims	6/146	4.11%
New compound + combination with metformin or paracetamol	2/146	1.37%
Compound + composition + combination	1/146	0.68%
Microparticle API (other than metformin or paracetamol) + composition + combination	1/146	0.68%
Combination + salt of a new compound	1/146	0.68%
Composition + co-administration	1/146	0.68%

Applying the above classification framework to the individual drugs reveals distinct patenting trends for metformin and paracetamol.

Metformin: Of the 86 patents relating to metformin, pharmaceutical combinations constitute the largest category, accounting for 50% (43/86) of the patents (Table 2). These primarily include fixed-dose combinations of metformin with other antidiabetic agents and related therapeutic compounds. Pharmaceutical compositions represent the second largest category, accounting for 31.40% (27/86) of the patents. The remaining patents fall into mixed categories. The largest of these groups consists of patents claiming another medicine together with its metformin salt, accounting for 8.14% (7/86). Patents covering both a pharmaceutical composition of a medicine and its combination with metformin account for 5.81% (5/86), while patents claiming another medicine together with its combination with metformin represent 2.33% (2/86). Other categories include patents claiming another medicine along with its pharmaceutical composition and its combination with metformin (1.16%, 1/86), and patents covering a microparticle form of another medicine together with its pharmaceutical composition and combination claims involving metformin (1.16%, 1/86).

Table 2: Metformin Patents

Category	Type	Patents	Share
Pharmaceutical combinations	Single	43/86	50.00%
Pharmaceutical compositions	Single	27/86	31.40%
New medicine + metformin salt	Mixed	7/86	8.14%
Pharmaceutical composition + combination with metformin	Mixed	5/86	5.81%
Another medicine + combination with metformin	Mixed	2/86	2.33%
Another medicine + composition + combination with metformin	Mixed	1/86	1.16%
Microparticle API + composition + combination with metformin	Mixed	1/86	1.16%
Total		**86**	**100%**

Paracetamol: Of the 60 patents relating to paracetamol, pharmaceutical compositions constitute the dominant category, accounting for 60.0% (36/60) of the patents (Table 3). These include paediatric formulations, microemulsions and stability-enhanced dosage forms. Pharmaceutical combinations account for 31.67% (19/60) of the patents and primarily relate to formulations combining paracetamol with anti-cold agents or other medicinal compounds. Two patents (3.33%, 2/60) relate to a structural derivative of paracetamol. The remaining patents fall into mixed categories. One patent covers both a pharmaceutical formulation and its use together with paracetamol, accounting for 1.67% (1/60) of the paracetamol patent set. Other mixed-category patents include one patent claiming a combination of paracetamol with a salt of a newly claimed medicine (1.67%, 1/60), and one patent covering both a pharmaceutical formulation and a drug combination involving paracetamol (1.67%, 1/60).

Table 3: Paracetamol Patents

Category	Type	Patents	Share
Pharmaceutical compositions	Single	36/60	60.00%
Pharmaceutical combinations	Single	19/60	31.67%
Derivatives (structural modifications)	Single	2/60	3.33%
Formulation + co-administration with paracetamol	Mixed	1/60	1.67%
Combination of paracetamol + salt of new medicine	Mixed	1/60	1.67%
Formulation + drug combination involving paracetamol	Mixed	1/60	1.67%
Total		**60**	**100%**

7 Case Studies

Case Study 1: Metformin Patent No. 438281 (Published 14 July 2023)

This patent, which belongs to Windlas Biotech Limited, discloses a single-layer extended-release tablet containing three APIs – metformin, voglibose and glimepiride – for the treatment of type 2 diabetes. Further, the patent also claims a small, lightweight tablet (no larger than 17 mm × 6 mm) designed to be easier for elderly patients to swallow.

The key objections raised by the patent examiner in the First Examination Report centred on:

- Lack of inventive step [Section 2(1)(ja) of the Patents Act]
- New form of an existing substance [S.3(d)]
- Lack of clarity of claims [S.10(5)]
- Insufficient disclosure [S.10(4)].

With regard to the objection on lack of inventive step, there were two instances of prior art which disclosed two already existing combinations, including a fixed-dose combination of extended release of metformin, voglibose and glimepiride. However, the patentee argued that the present product had a low weight, acceptable size and shape, and exhibited superior chemical and physical stability with extended release of metformin. The Indian Patent Office accepted the low weight as a technical advancement but did not apply the five-step test – prescribed in *F. Hoffmann-La Roche Ltd v. Cipla Ltd* (2015) by the Division Bench of the Delhi High Court (see Box 1) – to assess inventive step, despite mention of the test in the Manual of Patent Office Practice and Procedure (OCGPDTM, 2019). Further, a mere reduction in the physical dimensions of a tablet cannot be deemed as a technical advance under Section 2(1)(ja) of the Patents Act. It is important to note that irrespective of the five-step test, the Patent Office is expected to examine the obviousness of the invention under Section 2(1)(ja).

Box 1: Five-Step Test
Step No. 1: To identify an ordinary person skilled in the art. Step No. 2: To identify the inventive concept embodied in the patent. Step No. 3: To impute to a normal skilled but unimaginative ordinary person skilled in the art what was common general knowledge in the art at the priority date. Step No. 4: To identify the differences, if any, between the matter cited and the alleged invention and ascertain whether the differences are ordinary application of law or involve various different steps requiring multiple, theoretical and practical applications. Step No. 5: To decide whether those differences, viewed in the knowledge of alleged invention, constituted steps which would have been obvious to the ordinary person skilled in the art.

Regarding the objection under Section 3(d), the patentee argued that the claimed invention resulted in significant differences in safety and/or efficacy by decreasing the size of the tablet, and therefore that it was not a mere discovery of a new form of a known substance. The Patent Office should have demanded that the applicant demonstrate enhanced therapeutic efficacy of the present invention over prior art 2. No such data was demonstrated to overcome the objection. It is very clear that improvement in the physico-chemical properties (low weight, acceptable size and shape, and superior chemical and physical stability) or improved patient compliance is insufficient to satisfy the therapeutic efficacy requirement under Section 3(d) as stated in the Novartis judgement. In other words, any improvement in the physico-chemical properties needs to be supported by enhanced therapeutic efficacy data.

The Manual of Patent Office Practice and Procedure quotes the following paragraph of the Novartis judgement: "...the physico-chemical properties of beta crystalline form of Imatinib Mesylate, namely (i) more beneficial flow properties, (ii) better thermodynamic stability, and (iii) lower hygroscopicity, may be otherwise beneficial but these properties cannot even be taken into account for the purpose of the test of section 3(d) of the Act, since these properties have nothing to do with therapeutic efficacy." However, the patent examiner in the present case did not follow this instruction.

Further, the examiner failed to raise an objection under Section 3(e) although the patent claim included a multi-component combination, and no evidence on synergistic data of the combination product was produced comparing it with the individual medicinal compounds of metformin, voglibose and glimepiride. Section 3(e) bars patentability of combinations which lack synergistic effect and which lead only to aggregation of the properties of the components.

The patent effectively provides a statutory monopoly on a triple-therapy fixed-dose combination that exhibits only dimensional tweaks and minor structural differences – without any enhancement in glycaemic outcomes. Under a robust reading of Sections 2(1)(j)(a), 3(d) and 3(e), such a claim ought to have been rejected.

Table 4 summarizes other recently granted patents identified under the present study that include metformin in independent claim 1, and identifies the grounds of objection raised during the patent examination. The table is not intended to provide a detailed prosecution history of each patent. Rather, it captures the grounds of objection raised by the Indian Patent Office during the examination process up to grant, including those set out in the First Examination Report and any subsequent hearing notice.

Similarly, there were 27 metformin composition patents, many of which covered controlled-release, extended-release, delayed-release, osmotic, floating, gastro-retentive and other drug-delivery technologies. Several of these patents involved modified excipients, polymers, coatings, manufacturing processes, or variations in dosage strengths designed to alter the release profile of metformin. In many cases, the inventive concept appeared to revolve around reformulating a known pharmaceutical substance through modified delivery technologies rather than introducing a new therapeutic molecule. These are precisely the types of incremental pharmaceutical innovations that Section 3(d) was enacted to scrutinize, requiring evidence of enhanced therapeutic efficacy rather than mere improvements in formulation characteristics, release kinetics, stability or other minor technical modifications.

Table 4: Metformin-Related Patents and Grounds for Objection

S. No.	Applicant Name	Patent Number	Grant Publication Date	Claimed Subject Matter	Category of Product Patent	Grounds for Objection Raised During Patent Examination*
1.	Dr Ratheesh Rajendran & Dr Arun Jacob Thomas	IN438710A1	14-07-2023	Dental gel medicament containing metformin and calcium hydroxide	Combination	2(1)(j), 2(1)(ja), 3(d), 3(e), 10(4), 10(4)(c), 10(5)
2.	Lovely Professional University	IN413555A1	09-12-2022	Fixed-dose combination of metformin and naringin	Combination	2(1)(ja), 3(e), 3(i), 10(4)(c), 10(5)
3.	Dr Boggarapu Prakash Rao & Mrs Shravya Boggarapu	IN431610A1	19-05-2023	Oral liquid combination medicine containing metformin, teneligliptin, vitamin B12, atorvastatin and levothyroxine	Combination	2(1)(ja), 3(e), 3(i), 10(4)
4.	Amity University	IN420647A1	10-02-2023	Combination drug delivery system containing metformin and epicatechin	Combination	2(1)(j), 2(1)(ja), 3(e), 10(4)(c)
5.	Aizant Drug Research Solutions Private Limited	IN404894A1	02-09-2022	Pharmaceutical combination of metformin and glimepiride	Combination	2(1)(j), 2(1)(ja), 3(d), 3(e), 10(4)(c), 10(5)

* 2(1)(j) – lack of novelty [although Section 2(1)(j) defines an "invention", it is commonly cited by the Indian Patent Office when raising novelty objections]; 2(1)(ja) – lack of inventive step; 3(d) – new form of a known substance lacking enhanced therapeutic efficacy; 3(e) – mere admixture/composition lacking synergistic effect; 3(i) – method of treatment of humans and animals; 10(4) – insufficient disclosure or non-compliance with specification requirements; 10(4)(c) – scope of claims not clearly defined; 10(5) – claim lacks clarity, conciseness, definitiveness or support in the specification

Case Study 2: Paediatric Formulation of Paracetamol – Patent No. 416836 (Published 6 January 2023)

This patent covers a ready-to-use liquid paediatric composition of paracetamol with three other, inactive ingredients/excipients, viz., an oil phase, and a surfactant and co-surfactant which help the mixing of oil with water.

In the FER, the patent examiner cited the following objections:

- Lack of inventive step [S.2(1)(ja)]
- New form of an existing substance [S.3(d)]
- Mere admixture of known components [S.3(e)]
- Lack of clarity of claims [S.10(5)].

However, the patent was granted after hearing the patent applicant. Regarding inventive step, the applicant argued that the claimed invention exhibited technical advantages such as better drug loading capacity of paracetamol, a synergistic effect arising from the particle size of the paracetamol dispersion being less than 10nm, a reduced administration volume for paracetamol (250mg/2ml or 120mg/1ml) compared with marketed formulations (240mg/5ml), and absence of use of water as solvent, which leads to paracetamol stability. Therefore, according to the applicant, the invention demonstrated technical advance, was non-obvious to a person skilled in the art, and hence was inventive. However, the patent examiner did not apply the five-step test mentioned in the Patent Manual to establish inventive step.

Further, the applicant also argued that since the subject matter was inventive, it did not fall under Section 3(d). According to this line of argument, once an invention satisfies the inventive-step criterion, it can overcome the Section 3(d) hurdle. Such an interpretation would undermine the independent role of Section 3(d) as an additional patentability filter.

Regarding the objection under Section 3(e), the applicant argued that the paediatric formulation of paracetamol possessed synergistic effect by virtue of better drug loading capacity of paracetamol, a particle size of less than 10nm of paracetamol dispersion, reducing the volume of administration of paracetamol (250mg/2ml or 120mg/1ml) as compared with marketed formulations (240mg/5ml), and absence of use of water as solvent, which leads to paracetamol stability. However, the comparison of the pharmacological activity of the formulation should have been made with the activity of paracetamol alone and the individual activity, if any, of the inactive ingredients. Mere improvement in physico-chemical properties such as stability, solubility, drug loading or release profile may not by itself establish synergistic pharmacological action unless it is demonstrated that the combined formulation

exhibits greater therapeutic efficacy or pharmacological activity than the sum of the individual effects of its components.

Additionally, the Patent Office failed to raise an objection under Section 10(4)(a) regarding insufficient disclosure. The present claim did not disclose the process of making the paediatric pharmaceutical formulation of paracetamol. Though it disclosed a broad range of the three excipients along with paracetamol in the patent specification, it failed to disclose a general process of making a paediatric pharmaceutical formulation of paracetamol, nor did it disclose a specific process. Secondly, even though it disclosed a pharmaceutical composition of paracetamol formulation without forming precipitates in the presence of water (page 6 of the specification, paragraph 4), it did not provide any experimental support for the findings. Thirdly, it disclosed that the paracetamol formulation of the present invention results in the formation of nanoemulsion *in vivo*. However, it failed to disclose any clinical data to substantiate the claim. Thus, the specification did not enable a person with average skill and knowledge to make the paracetamol paediatric formulation.

Table 5 presents details of five recently granted patents identified under the present study that include paracetamol in independent claim 1, together with the grounds of objection raised during patent examination. However, the table does not provide a comprehensive account of the prosecution history of these patents. The grounds of objection reported in the table comprise those raised by the Indian Patent Office during examination up to the grant of the patent, including objections contained in the FER and any subsequent hearing notice.

Table 5: Paracetamol-Related Patents and Grounds for Objection

S. No.	Applicant Name	Patent Number	Grant Publication Date	Claimed Subject Matter	Category of Product Patent	Grounds for Objection Raised During Patent Examination*
1.	Troikaa Pharmaceuticals Limited	IN411067A1	11-11-2022	A concentrated paracetamol injection	Composition	2(1)(j), 2(1)(ja), 3(d), 3(e), 3(i), 10(4)(c), 10(5)
2.	Shilpa Medicare Limited	IN365019A1	23-04-2021	A mouth-dissolving paracetamol strip	Composition	2(1)(ja), 3(d), 3(e), 10(4)(c), 10(5)
3.	M.S. Ramaiah University of Applied Sciences	IN360017A1	05-03-2021	Modified paracetamol compounds	Derivative	2(1)(ja), 3(d), 3(e), 10(4), 10(4)(c), 10(5)
4.	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. & Tseti, Ioulia	IN358983A1	26-02-2021	Ready-to-use paracetamol injection	Composition	2(1)(ja), 3(d), 3(e), 10(4)(c), 10(5)
5.	Bhaumik Pandya, Dr Shreeraj Shah & Dr Nihar Shah	IN348906A1	16-10-2020	A fixed-dose combination of paracetamol and vitamin E	Combination	2(1)(j), 2(1)(ja), 3(d), 3(e), 3(i), 10(4)(c), 10(5)

* 2(1)(j) – lack of novelty [although Section 2(1)(j) defines an "invention", it is commonly cited by the Indian Patent Office when raising novelty objections]; 2(1)(ja) – lack of inventive step; 3(d) – new form of a known substance lacking enhanced therapeutic efficacy; 3(e) – mere admixture/composition lacking synergistic effect; 3(i) – method of treatment of humans and animals; 10(4) – insufficient disclosure or non-compliance with specification requirements; 10(4)(c) – scope of claims not clearly defined; 10(5) – claim lacks clarity, conciseness, definitiveness or support in the specification

Across the 36 paracetamol composition patents, 19 combination patents and two derivative patents, the claimed inventions largely relate to flavoured syrups, oral liquids, paediatric formulations, suspensions, microcapsules, microemulsions, controlled-release formulations, injectable formulations and modified excipient systems. Several patents also claim fixed-dose combinations of paracetamol with antihistamines, decongestants, anti-inflammatory agents or other therapeutic compounds. The derivative patents involve structural modifications of paracetamol, including the synthesis of new paracetamol-based compounds intended to provide analgesic, antipyretic or anti-inflammatory effects. Collectively, these patents predominantly represent incremental modifications to known pharmaceutical products already available in the market, focusing on formulation design, delivery systems, palatability, stability, manufacturability, combinations of known medicines, or structural variations of a known molecule. In the absence of evidence demonstrating enhanced therapeutic efficacy in the case of derivative and formulation patents, or a synergistic effect in the case of combination patents, such inventions ought not to have satisfied the threshold requirements under Sections 3(d) and 3(e) of the Patents Act.

(See Annexes 2 and 3 for a more detailed background of the two patents assessed in the case studies above.)

8 Accountability of the Indian Patent Office

The Indian Patent Office has granted multiple patents on molecules that have been in therapeutic use for over 70 years, effectively bypassing the statutory safeguards embedded in the Patents Act. These safeguards were incorporated by Parliament to prevent the practice of evergreening – the successive patenting of minor modifications to known substances to extend monopoly. The Patent Office, entrusted with the responsibility of applying these provisions as a gatekeeper, has instead demonstrated a consistent pattern of non-compliance, as documented by prior studies and reaffirmed by the present analysis.

Both the case studies above clearly show that the Patent Office interpreted inventive step contrary to the legislative intent and fully disregarded the Section 3(d) scrutiny by not seeking evidence of enhanced efficacy, a requirement detailed in the Novartis judgement. In the case of combinations, the Patent Office again often interprets inventive step contrary to the legislative intent and does not seek evidence of synergistic effect for pharmaceutical combination products.

Weak Enforcement of Section 3(d)

Of the 146 patents analyzed, 63 claim pharmaceutical compositions – 27 on metformin and 36 on paracetamol; and 62 claim combinations – 43 on metformin and 19 on paracetamol. These grants raise serious questions regarding both inventive step and compliance with Section 3(d) of the Patents Act.

According to the Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals, "Section 3(d) stipulates that an incremental invention, based upon an already known substance, having established medicinal activity shall be deemed to be treated as a same substance, and shall fall foul of patentability, if the invention in question fails to demonstrate significantly improved therapeutic efficacy with respect to that known compound" (OCGPDTM, 2014). The Guidelines for Examination further quote the Novartis judgement of the Supreme Court: "However, in case of chemicals and especially pharmaceuticals if the product for

which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass, in addition to clauses (j) and (ja) of section 2(1), the test of enhanced efficacy as provided in section 3(d) read with its explanation."

Yet, the present study reveals that the Patent Office practice differs from its own Guidelines for Examination and the Patent Office has routinely granted patents for:

- Minor formulation modifications – altered excipients, layer structure or tablet size
- Fixed-dose combinations of already existing medicines
- Incremental convenience features such as improved flavour or palatability including in paediatric formulations.

None of these changes constitute enhanced therapeutic efficacy. The above case study on the paracetamol patent shows that the Patent Office accepted the argument of the patent applicant that once the patent subject matter satisfies the inventive-step criterion, Section 3(d) does not apply. This reasoning goes against not only the Supreme Court's Novartis judgement but also the Guidelines for Examination. It is important to note that both metformin and paracetamol have been in therapeutic use for more than 70 years and the Patent Office granted 86 patents on metformin and 60 patents on paracetamol during the period under study. The number of patents claiming metformin as an independent claim (claim 1) is 35, while a total of 30 patents covered paracetamol in claim 1. This clearly shows the scale and gravity of disregard for Section 3(d) and the legislative intent behind it.

Undermining of Section 3(e)

According to the Guidelines for Examination, "Claims related to compositions obtained by mere admixture resulting in aggregation of the properties of the individual components are not patentable under section 3(e) of Act. However, in a composition if the functional interaction between the features achieves a combined technical effect which is greater than the sum of the technical effects of the individual features, it indicates that such a composition is more than a mere aggregation of the features" (OCGPDTM, 2014). Further, the Manual of the Patent Office states: "In general, all the substances which are produced by mixing components or a process of producing such substances should satisfy the requirement of synergistic effect in order to be patentable. Synergistic effect should be clearly brought out in the description by way of comparison at the time of filing of the Application itself. The subsequent submissions regarding synergism can be accepted in a reply to the office action as a further support of synergy" (OCGPDTM, 2019). Thus, a patent claim on a pharmaceutical combination is permissible only where the patent

applicant provides evidence of synergistic effect, i.e., the interaction between two or more drugs where their combined effect is significantly greater than the sum of their individual effects. The present study finds that combination patents have been routinely granted in the absence of any such evidence.

Consequences

The Patent Office's approach reflects a disposition to facilitate patent grants rather than rigorously scrutinize them, resulting in inconsistent and legally untenable application of Section 3(d) and Section 3(e). Several downstream consequences follow:

Evergreening and Delayed Generic Entry: The above discussion shows that the Patent Office is not functioning as a gatekeeper to implement the law in a manner reflecting the legislative intent, but rather is apparently devising ways to manufacture patents on behalf of patent applicants. The Patent Office follows an inconsistent stand that disregards the Supreme Court interpretation of Section 3(d) and makes it vulnerable to undue influence by external actors, including patent applicants. The disregard of the legal safeguards would result in the proliferation of evergreening patents. This lack of accountability of the Patent Office could directly affect access to medicines by delaying the entry of affordable generics into the market. The risk is not theoretical – the wrongful grant of a patent on risdiplam, a molecule already in the public domain due to a prior patent in another jurisdiction, directly delayed the entry of generic versions of this life-saving medicine. Similarly, a single originator company has filed nearly 18 patent applications on the long-acting antiviral lenacapavir, which, if granted, would extend monopoly control by approximately eight years beyond the expiry of the first patent (TWN, 2025).

Chilling Effect on Domestic Innovation: Further, multiple patents on known molecules could create a chilling effect on innovation. The accumulation of 86 patents on metformin and 60 on paracetamol does not merely affect market competition – it creates a legal risk for domestic manufacturers seeking to develop new formulations around these molecules. Non-granting of patents would have allowed domestic manufacturers the freedom to bring the product into the market without fear of legal infringement. Thus, a rigorous application of patentability safeguards would provide greater freedom of operation instead of blocking business opportunities.

Impact on Drug Pricing and Access: Besides delaying the entry of generics, lax patenting can also undermine affordable access to medicines by affecting application of the Drugs (Prices Control) Order, 2013 which regulates medicine prices. Paragraph 32(i) of the DPCO excludes from application of the Order "a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (39 of

1970), for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country" (Government of India, 2013). The definition of "new drugs" under the New Drugs and Clinical Trials Rules, 2019 (CDSCO, 2019) includes new active pharmaceutical ingredients, new sustained releases, new fixed-dose combinations, modified or new claims including indication, route of administration, dosage and dosage form etc. Accordingly, patents on such claims can readily secure a five-year exemption from price control, with direct implications for affordability.

Quantity Over Quality: At a time when India is investing significantly in its own API manufacturing capacity and domestic vaccine production in line with its identity as "the pharmacy of the developing world", in both generics and biosimilars, the functioning of its patent system assumes strategic importance. However, the Patent Office is following a high-grant, low-scrutiny model – one that accumulates a large portfolio of patents in force, many of them foreign-owned, weakly examined and rarely declared as worked in the territory of India. This path risks creating deadweight rights and constraining domestic production capacity – the very capacity that India is seeking to advance.

This approach has resulted in the granting of patents in conflict with the provisions of the Patents Act. Consistent application of the safeguards embedded in the Act would protect access to medicines, enable innovation by allowing domestic manufacturers to operate without the chilling effect from questionable patent grants, and reinforce India's leading global position in pharmaceutical production.

9 Conclusions and Key Suggestions

This study demonstrates that the Indian Patent Office has granted multiple product patents on metformin and paracetamol – molecules that have been in therapeutic use for over 70 years. The granted claims reveal that the Patent Office has systematically lowered the threshold for inventive step and failed to apply the scrutiny mandated under Section 3(d) and 3(e) of the Patents Act – provisions which are explicitly designed to prevent patent evergreening in India. This constitutes a clear departure from the legislative intent, with the Patent Office failing to apply the safeguards related to scope of patentability in its patent examinations and granting patents in clear contravention of the provisions of the Patents Act. As prior studies have documented, this has resulted in the granting of thousands of legally untenable patents (Ali et al., 2018). The emphasis on quantity over quality represents the failure of the Patent Office as a gatekeeper, with direct consequences for India's innovation ecosystem and industrial self-reliance and compromising the government's obligation to uphold the enjoyment of human rights, including the right to health and right to science.

Granting of patents for such old molecules goes against the very objective of patents as a tool to promote innovation. The rationale for the patent system is to incentivize disclosure by granting a 20-year statutory monopoly, after expiry of which the subject matter enters the public domain for free use. The large number of product patents covering only minor modifications of these two old molecules means that, despite the expiry of the primary patents on metformin and paracetamol, these molecules have not effectively entered the public domain. Instead, secondary patents continue to be granted for trivial variations, thereby extending exclusivity over subject matter that would otherwise be freely available for public use, undermining the very foundations of the patent system.

Key Recommendations

We propose the following measures for stricter implementation of the safeguards against the evergreening of patents.

Update Examination Guidelines and the Manual of Patent Office Practice and Procedure: The Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals and the Manual of Patent Office Practice and Procedure require urgent revision to accurately reflect legislative intent. In addition, the Guidelines and the Manual should be reviewed and updated on a periodic basis, preferably annually, to incorporate developments in patent jurisprudence, including landmark decisions of the Supreme Court and High Courts. Such regular updates would help ensure consistency in patent examination and prevent divergence from the evolving legal standards. Further, the Patent Office should amend its examination process and introduce a two-phase approach. In the first phase, the examiner needs to examine whether the claimed invention falls within the statutory exclusions mentioned in Section 3. The Patent Office has to carry out the second phase of the examination (substantive examination) – i.e., whether the patent application satisfies the patentability criteria – only if it has been determined that the application does not fall under the Section 3 statutory exclusions. The Manual should be amended to incorporate this two-phase approach to patent examination. Critically, the revised Guidelines should include a dedicated evergreening checklist for examiners, setting out clear, structured criteria to identify and reject applications that seek to patent known substances without demonstrating enhanced therapeutic efficacy (Ali et al., 2018). The Guidelines should also document and address strategies commonly deployed by patent applicants to circumvent the safeguards against evergreening, especially Section 3(d) and Section 3(e).

Revoke Wrongfully Granted Patents: Patents granted in contravention of the provisions of the Patents Act should be revoked. Section 66 of the Act provides the necessary legal authority empowering the government to revoke a patent in the public interest. According to Section 66: "Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked." The granting of patents contrary to the provisions of the Act can be seen as prejudicial to the public. The Government of India has previously exercised its power under Section 66 to revoke patents. In 1994, a patent granted to Agracetus, a US company, for genetically engineered cotton cell lines was revoked for being prejudicial to farmers' rights and the cotton industry (Gopikrishnan and Patel, 2014). Similarly, in 2012, a patent held by biotech firm Avesthagen was revoked on the ground that the claimed invention was part of traditional knowledge (Sidhartha, 2012).

Reform Examiners' Training: Patent examiners must receive regular, structured training grounded in Indian patent jurisprudence and the legislative intent of the Patents Act, and which reflects national social, economic and technological prior-

ities. Training programmes carried out jointly with foreign patent offices bear the risk of transplanting foreign examination practices which depart from the legislative intent of the Patents Act. Such programmes should be reviewed to ensure alignment with Indian laws. Training must also cover foundational legal principles including the duty to pass reasoned orders and the right to be heard.

Mandate Reasoned Orders: It is a recurrent and documented pattern – observed in prior studies and confirmed in the present analysis – that patent examiners raise legally valid objections in the First Examination Report but subsequently accept applicants' responses without providing any reasoning. Such non-speaking orders violate the principles of natural justice. It should be made mandatory for examiners to issue reasoned orders when granting patents, particularly when accepting arguments made in response to FER objections. This requirement would enhance accountability, enable appellate review and deter arbitrary decision making.

Prioritize Quality Over Quantity: The Indian Patent Office's current performance metrics incentivize volume over rigour, focusing on quantity over quality. In 2024–25, the Patent Office disposed of 40,606 patent applications and issued 33,504 grants (OCGPDTM, 2025). Thus, it granted patents for some 83% of the applications it examined. This rate has remained consistently high over several years and stands in stark comparison to other jurisdictions: the United States Patent and Trademark Office (USPTO) maintains a grant rate of below 55%. In 2023–24 the Indian Patent Office granted 103,057 patents with only 219 patent examiners – an average of approximately 470 grants per examiner (OCGPDTM, 2025). This is unsustainable and incompatible with rigorous examination. Performance indicators must be reevaluated to reward examination quality and not quantity.

Establish an Independent Audit Mechanism: An independent expert panel should be constituted to conduct periodic audits of granted patents, with a continuous mandate to identify patents granted contrary to provisions of the Patents Act. Continuous quality monitoring would provide an institutional check on the Patent Office's gatekeeping function, generate evidence for systematic reform and create accountability for the Patent Office.

Amend Section 3(d): Section 3(d), as currently framed, operates on a case-by-case basis, with the Patent Office assessing each patent application on a known substance on its merits. While this was intended as a robust safeguard, the present as well as prior studies demonstrate that this discretion has been applied inconsistently and is vulnerable to undue influence.

In light of this, there is a need to consider an amendment of Section 3(d) to explicitly exclude evergreening patents by limiting the scope of patentability to new chemical entities only. Towards this end, an expert committee under the chairmanship of Dr R.A. Mashelkar was appointed by the Indian government in 2005 to determine, among others, "whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity or to new medical entity involving one or more inventive steps" (Technical Expert Group on Patent Law Issues, 2006). The committee reached the conclusion that such a limitation would not be compatible with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), without however engaging substantively with the arguments in favour of such a limitation or providing adequate legal reasoning. Multiple submissions before the committee had argued in favour of TRIPS compatibility; these arguments were not addressed (Gopakumar, 2009). A definitive evidence-based amendment to Section 3(d) – one that establishes a bright line standard limiting patentability to new chemical entities – would be a durable and effective mechanism to prevent evergreening of patents.

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Annex 1

Details of Relevant Granted Patents of Metformin							
Metformin							
Serial No.	**Patent Number**	**Application Number**	**Application/Filing Date**	**Publication Date**	**Title**	**Priority Date**	**Applicant Name**
1	IN438710A1	IN202241054795	2022-09-24	2023-07-13	NOVEL MEDICAMENT GEL WITH METFORMIN AND CALCIUM HYDROXIDE	2022-09-24	DR RATHEESH RAJENDRAN, DR ARUN JACOB THOMAS
2	IN438281A1	IN202211025910	2022-05-04	2023-07-14	TRIPLE COMBINATION	2022-05-04	WINDLAS BIOTECH LIMITED
3	IN413555A1	IN202111046678	2021-10-13	2022-12-09	NOVEL COMPOSITION FOR THE TREATMENT OF DIABETIC NEUROPATHY AND PROCESS THEREOF	2021-10-13	LOVELY PROFESSIONAL UNIVERSITY
4	IN390470A1	IN202121032098	2021-07-16	2022-03-04	FLOATING MICROPOROUS OSMOTIC TABLET	2021-07-16	DR PRABHA SINGH
5	IN431610A1	IN202141014729	2021-03-31	2023-05-19	AN ORAL LIQUID FORMULATION OF METFORMIN, TENELIGLIPTIN, VITAMIN 12, ATORVASTATIN AND LEVOTHYROXINE FOR DIABETES	2021-03-31	DR BOGGARAPU PRAKASH RAO, MRS SHRAVYA BOGGARAPU
6	IN394144A1	IN202141012333	2021-03-22	2022-04-08	A METFORMIN VAGINAL COMPOSITION FOR POLYCYSTIC OVARIAN SYNDROME	2021-03-22	DR RAJESHRI DHURKE
7	IN377566A1	IN201911047438	2019-11-20	2021-09-24	CONTROLLED RELEASE METFORMIN COMPOSITIONS	2019-11-20	WINDLAS BIOTECH LIMITED

Details of Relevant Granted Patents of Metformin							
Metformin							
Serial No.	**Patent Number**	**Application Number**	**Application/Filing Date**	**Publication Date**	**Title**	**Priority Date**	**Applicant Name**
8	IN334363A1	IN201928027472	2019-07-09	2020-03-13	PHARMACEUTICAL COMPOSITIONS OF REMOGLIFLOZIN AND METFORMIN	2019-07-09	GLENMARK PHARMACEUTICALS LIMITED
9	IN388600A1	IN201847023657	2018-06-25	2022-02-11	EFFERVESCENT COMPOSITIONS OF METFORMIN AND PROCESSES FOR PREPARATION THEREOF	2018-06-25	STEERLIFE INDIA PRIVATE LIMITED
10	IN387049A1	IN201847019240	2018-05-23	2022-01-28	COMPOSITION FOR TREATING DIABETES	2018-05-23	KATO, YASUMASA
11	IN431663A1	IN201727043838	2017-12-07	2023-05-19	INHIBITOR OF IGFBP3/TMEM219 AXIS AND DIABETES	2017-12-07	OSPEDALE SAN RAFFAELE SRL
12	IN383907A1	IN201717022449	2017-06-27	2021-12-10	CONTROLLED RELEASE OF ACTIVE SUBSTANCES	2017-06-27	SOCIETE DEXPLOITATION DE PRODUITS POUR LES INDUSTRIES CHIMIQUES SEPPIC
13	IN417421A1	IN201721021519	2017-06-20	2023-01-13	HOT MELT EXTRUDED/ GRANULATED DIRECTLY COMPRESSIBLE API'S/ EXCIPIENTS BY MELT GRANULATION TECHNOLOGY	2017-06-20	PURNIMA D. AMIN
14	IN353917A1	IN201717017097	2017-05-16	2020-12-25	COMPOSITE PREPARATION CONTAINING NOVEL 3 (4 (BENZYLOXY)PHENYL)HEX 4 INOIC ACID DERIVATIVE AND ANOTHER ACTIVE INGREDIENT FOR PREVENTING OR TREATING METABOLIC DISEASES	2017-05-16	HYUNDAI PHARM CO. LTD.

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15	IN394197A1	IN201721012521	2017-04-07	2022-04-08	EFFERVESCENT COMPOSITIONS COMPRISING SAXAGLIPTIN OR SALT THEREOF	2017-04-07	ZENVISION PHARMA LLP
16	IN420647A1	IN201711005476	2017-02-16	2023-02-10	FILOMICELLES OF COMBINATION DRUGS FOR THE TREATMENT OF BRAIN DIABETES	2017-02-16	AMITY UNIVERSITY
17	IN404894A1	IN201641011014	2016-03-30	2022-09-02	PHARMACEUTICAL COMPOSITIONS OF METFORMIN AND GLIMEPIRIDE	2016-03-30	AIZANT DRUG RESEARCH SOLUTIONS PRIVATE LIMITED
18	IN367298A1	IN3416MUMNP2015	2015-12-02	2021-05-28	SYNERGISTIC COMPOSITION COMPRISING COMPOUND OF FORMULA (Ia)	2015-12-02	CADILA HEALTHCARE LIMITED
19	IN335902A1	IN5858DELNP2015	2015-07-03	2020-05-01	DELAYED RELEASE COMPOSITION COMPRISING BIGUANIDE	2015-07-03	ANJI PHARMA (US) LLC
20	IN301257A1	IN3942MUM2014	2014-12-09	2018-09-28	PHARMACEUTICAL COMPOSITION COMPRISING METFORMIN	2014-12-09	BAKSHI, AMIT
21	IN347985A1	IN1625MUM2014	2014-05-12	2020-10-02	ORAL COMPOSITIONS AND PROCESSES FOR PREPARING DIFFERENT DOSAGE FORMS COMPRISING OF CONTROLLED RELEASE MULTI UNIT PARTICULATE SYSTEM	2014-05-12	MR MUNDADA PIYUSH KISHOR, MRS MUNDADA VEENU PIYUSH, DR (MRS) SAWANT KRUTIKA KHANDERAO

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Serial No.	**Patent Number**	**Application Number**	**Application/Filing Date**	**Publication Date**	**Title**	**Priority Date**	**Applicant Name**
22	IN371501A1	IN5103CHE2013	2013-11-11	2021-07-16	COMPOSITION FOR MANAGEMENT OF MYELOPROLIFERATIVE DISORDER, PROCESS FOR PREPARATION AND KIT THEREOF	2013-11-11	CELLWORKS GROUP, INC.
23	IN310351A1	IN10658CHENP2012	2012-12-21	2019-04-05	PHARMACEUTICAL COMPOSITION COMPRISING METFORMIN AND GLUCOKINASE ACTIVATOR	2012-12-21	vTv THERAPEUTICS LLC
24	IN328742A1	IN4654CHE2012	2012-11-06	2020-01-03	A FORMULATION OF IN SITU GELLING DRUG DELIVERY SYSTEM FOR DIABETES	2012-11-06	KARNATAKA COLLEGE OF PHARMACY
25	IN284447A1	IN6003DELNP2012	2012-07-05	2017-06-23	PHARMACEUTICAL COMPOSITION COMPRISING METFORMIN AND ROSUVASTATIN	2012-07-05	BCWORLD PHARM. CO. LTD.
26	IN306839A1	IN1864DELNP2012	2012-03-01	2019-02-08	FLOATING MICROGRANULES	2012-03-01	DEBREGEAS ET ASSOCIES PHARMA
27	IN312847A1	IN639DELNP2012	2012-01-23	2019-05-24	COMBINATION THERAPY FOR THE TREATMENT OF DIABETES	2012-01-23	JANSSEN PHARMACEUTICA, N.V.
28	IN293282A1	IN8468CHENP2011	2011-11-17	2018-03-02	PHARMACEUTICAL COMPOSITIONS COMPRISING CONTROLLED RELEASE FLOATING MICROPARTICLES	2011-11-17	FLAMEL IRELAND LIMITED

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29	IN320937A1	IN6152DELNP2011	2011-08-12	2019-09-27	PHARMACEUTICAL COMPOSITION COMPRISING A SGLT2 INHIBITOR, A DPP-IV INHIBITOR AND OPTIONALLY A FURTHER ANTIDIABETIC AGENT AND USES THEREOF	2011-08-12	BOEHRINGER INGELHEIM INTERNATIONAL GMBH
30	IN276357A1	IN805MUMNP2011	2011-04-22	2016-10-17	PHARMACEUTICAL COMPOSITION FOR PREVENTION AND TREATMENT OF DIABETES OR OBESITY COMPRISING A COMPOUND THAT INHIBITS ACTIVITY OF DIPEPTIDYL PEPTIDASE-IV, AND OTHER ANTIDIABETIC OR ANTIOBESITY AGENTS AS ACTIVE INGREDIENTS	2011-04-22	DONG-A SOCIO HOLDINGS CO LTD
31	IN306043A1	IN2211DELNP2011	2011-03-25	2019-01-25	METHOD OF TREATING DYSGLYCEMIA AND GLUCOSE EXCURSIONS	2011-03-25	MACGREGOR ALEXANDER
32	IN316227A1	IN8974DELNP2010	2010-12-15	2019-07-19	GLUCAGON/GLP-1 RECEPTOR CO-AGONISTS	2010-12-15	INDIANA UNIVERSITY RESEARCH AND TECHNOLOGY CORPORATION
33	IN284176A1	IN8480DELNP2010	2010-11-30	2017-06-16	NOVEL COMPOSITION FOR TREATING HYPERPROLIFERATIVE DISEASES	2010-11-30	ALS MOUNTAIN LLC
34	IN276386A1	IN2472KOLNP2010	2010-07-07	2016-10-18	COMPRESSED CHEWING GUM TABLET	2010-07-07	FERTIN PHARMA A/S

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35	IN281903A1	IN584KOLNP2010	2010-02-15	2017-03-31	SOLID PREPARATION COMPRISING ALOGLIPTIN AND METFORMIN HYDROCHLORIDE	2010-02-15	TAKEDA PHARMACEUTICAL COMPANY LIMITED
36	IN345498A1	IN2955MUM2009	2009-12-22	2020-09-04	CONTROLLED RELEASE PHARMACEUTICAL COMPOSITION	2009-12-22	ABBOTT HEALTHCARE PRIVATE LIMITED
37	IN291470A1	IN2375MUM2009	2009-10-12	2018-01-12	PHARMACEUTICAL COMPOSITIONS	2009-10-12	IPCA LABORATORIES LIMITED
38	IN286235A1	IN4127CHENP2009	2009-07-14	2017-08-18	FUSED AROMATIC PTP-IB INHIBITORS	2009-07-14	KANEQ PHARMA INC.
39	IN271908A1	IN468MUM2009	2009-03-04	2016-03-09	A NOVEL ORAL CONTROLLED RELEASE DOSAGE FORMS FOR WATER SOLUBLE DRUGS	2009-03-04	FDC LIMITED
40	IN260436A1	IN2047MUM2008	2008-09-24	2014-05-02	PHARMACEUTICAL COMPOSITIONS FOR THE TREATMENT OF DIABETES MELLITUS	2008-09-24	IPCA LABORATORIES LIMITED
41	IN265228A1	IN4694CHENP2008	2008-09-05	2015-02-13	AMINOTETRAHYDROPYRANS AS DIPEPTIDYL PEPTIDASE-IV INHIBITORS FOR THE TREATMENT OR PREVENTION OF DIABETES	2008-09-05	MERCK SHARP & DOHME CORP.
42	IN297753A1	IN2061CHE2008	2008-08-25	2018-06-22	OSMOTIC CONTROLLED RELEASE DOSAGE FORM OF METFORMIN	2008-08-25	MYLAN LABORATORIES LTD.

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43	IN297811A1	IN6995DELNP2008	2008-08-14	2018-06-22	A PHARMACEUTICAL COMPOSITION	2008-08-14	AXCESS LIMITED
44	IN269686A1	IN3244KOLNP2008	2008-08-07	2015-10-30	COMBINATION OF TRIAZINE DERIVATIVES AND INSULIN SENSITISERS	2008-08-07	MERCK PATENT GMBH
45	IN269661A1	IN239KOLNP2008	2008-01-17	2015-10-30	GASTRORETENTIVE FORMULATIONS AND MANUFACTURING PROCESS THEREOF	2008-01-17	ETHYPHARM
46	IN257100A1	IN5938DELNP2007	2007-07-30	2013-09-06	CONTROLLED RELEASE COMPLEX FORMULATION FOR ORAL ADMINISTRATION OF MEDICINE FOR DIABETES AND METHOD FOR THE PREPARATION THEREOF	2007-07-30	HANMI PHARM. CO., LTD
47	IN280713A1	IN1654DELNP2007	2007-03-01	2017-03-03	ANTIDIABETIC ORAL INSULIN-BIGU ANIDE COMBINATION	2007-03-01	EMISPHERE TECHNOLOGIES, INC.
48	IN247582A1	IN1411MUM2006	2006-09-04	2011-04-29	A SYSTEM FOR SPATIALLY AND TEMPORALLY PROGRAMMABLE DELIVERY OF AN ACTIVE AGENT	2006-09-04	PANACEA BIOTEC LTD.
49	IN268846A1	IN4844DELNP2006	2006-08-23	2015-09-18	GLUCOPYRANOSYL-SUBSTITUTED BENZENOL DERIVATIVES, DRUGS CONTAINING SAID COMPOUNDS, THE USE THEREOF AND METHOD FOR THE PRODUCTION THEREOF	2006-08-23	BOEHRINGER INGELHEIM INTERNATIONAL GMBH.

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50	IN249226A1	IN1230MUM2006	2006-08-03	2011-10-21	ION EXCHANGE RESIN BASED EXTENDED RELEASE GASTRO-RETENTIVE DOSAGE FORMS	2006-08-03	AMIN, PURNIMA DHANRAJ
51	IN236269A1	IN4136DELNP2006	2006-07-18	2009-10-23	PHARMACEUTICAL COMPOSITION COMPRISING METFORMIN AND FIBRATE ANS PROCESS FOR PREPARATION THEREOF	2004-01-23	FOURNIER LABORATORIES IRELAND LIMITED
52	IN290266A1	IN2665DELNP2006	2006-05-11	2017-12-08	HETEROCYCLIC BORONIC ACID COMPOUNDS	2006-05-11	PHENOMIX CORPORATION
53	IN251197A1	IN610CHE2006	2006-04-03	2012-03-02	NOVEL DIPEPTIDYL PEPTIDASE IV INHIBITORS, PROCESSES FOR THEIR PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM	2006-04-03	MATRIX LABORATORIES LTD.
54	IN223463A1	IN2173CHENP2005	2005-09-06	2008-11-21	COMPOSITION COMPRISING THERAPEUTIC AGENTS FOR TREATING DIABETES	2003-02-07	AJINOMOTO CO., INC
55	IN246255A1	IN819KOLNP2005	2005-05-05	2011-02-25	SOLID PREPARATION COMPRISING AN INSULIN SENSITIZER AND AN ACTIVE INGREDIENT	2002-10-07	TAKEDA PHARMACEUTICAL COMPANY LIMITED
56	IN218826A1	IN711CHENP2005	2005-04-25	2008-05-23	COMBINATION DRUG	2002-09-26 2003-04-23	EISAI R & D MANAGEMENT CO. LTD

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57	IN262044A1	IN321MUM2005	2005-03-22	2014-08-01	NOVEL MULTIPLYING POROUS OSMOTIC AND DIFFUSION DRUG DELIVERY SYSTEM	2005-03-22	CADILA HEALTHCARE LIMITED
58	IN229618A1	IN889MUM2004	2004-08-16	2009-03-27	A MULTIPLE RELEASE ANTIDIABETIC PHARMACEUTICAL TABLET COMPOSITION	2004-08-16	M/S. IPCA LABORATORIES LIMITED
59	IN224907A1	IN1431CHENP2004	2004-06-25	2008-12-05	PHARMACEUTICAL COMPOSITIONS COMPRISING METFORMINE AND GLIBENCLAMIDE	2001-11-29	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S.A
60	IN244433A1	IN557MUM2004	2004-05-14	2010-12-10	A CONTROLLED RELEASE DELIVERY COMPOSITION OF METFORMIN	2004-05-14	CADILA HEALTHCARE LIMITED
61	IN233453A1	IN197MUM2004	2004-02-20	2009-03-27	NOVEL DOSAGE FORM	2004-02-20	TORRENT PHARMACEUTICALS LTD.
62	IN244585A1	IN198MUM2004	2004-02-20	2010-12-17	NOVEL DRUG DELIVERY SYSTEM	2004-02-20	TORRENT PHARMACEUTICALS LTD.
63	IN209309A1	IN127MUMNP2004	2004-02-19	2008-10-17	A MONOLITHIC SUSTAINED RELEASE COMPOSITION OF METFORMIN HYDROCHLORIDE	2000-10-02	USV LIMITED

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64	IN206100A1	IN130MUM2004	2004-02-05	2007-07-13	STABLE ORAL ANTIDIABETIC FORMULATION OF GLIPIZIDE AND METFORMIN HYDROCHLORIDE	2004-02-05	USV LIMITED
65	IN202870A1	IN736MUM2003	2003-07-23	2007-04-13	NOVEL PHARMACEUTICAL COMBINATION COMPRISING OF A BIGUANIDE AND AN INSULIN ENHANCER AND FORMULATED COMPOSITION THEREOF FOR ORAL USE	2003-07-23	M/S IPCA LABORATORIES LIMITED
66	IN221690A1	IN448CHE2003	2003-06-03	2008-09-12	NOVEL ANTIINFECTIVE COMPOUNDS AND THEIR PHARMACEUTICAL COMPOSITIONS	2003-06-03	DR. REDDY'S LABORATORIES LTD.
67	IN211653A1	IN442MUMNP2003	2003-04-23	2008-01-25	MEDICINE BASED ON ANTI-HYPERGLYCEMIC MICROCAPSULES WITH PROLONGED RELEASE AND METHOD FOR PREPARING SAME	2000-11-17	FLAMEL TECHNOLOGIES
68	IN216471A1	IN108CHE2003	2003-02-07	2008-03-31	NEW ANTICANCER COMPOUNDS : PROCESS FOR THEIR PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM	2003-02-07	DR. REDDY'S LABORATORIES LTD.

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69	IN204729A1	ININPCT20021874 MUM	2002-12-24	2007-06-22	ORAL PHARMACEUTICAL COMPOSITION WITH CONTROLLED RELEASE AND PROLONGED ABSORPTION	2000-07-11	FLAMEL TECHNOLOGIES
70	IN204082A1	ININPCT20021246 MUM	2002-09-12	2007-05-25	A COMPOUND O-ARYL GLUCOSIDE AND A PHARMACEUTICAL COMPOSITION THEREOF	2002-09-12	BRISTOL-MYERS SQUIBB COMPANY
71	IN210875A1	ININPCT2002873 DEL	2002-09-04	2007-11-09	"A CLEAR AQUEOUS SOLUTION"	2000-02-04	YOO, SEO, HONG
72	IN206543A1	ININPCT20021154 MUM	2002-08-23	2007-07-27	A CYCLOPROPYL-FUSED PYRROLIDINE-BASED COMPOUND	2000-03-10	BRISTOL-MYERS SQUIBB COMPANY
73	IN211238A1	ININPCT2002880 MUM	2002-07-01	2007-11-09	THE SUBSTANCE 5-CHLORO-N-[2-[4-[[[(CYCLOHEXYLAMINO)-CARBONYL)AMINO] SULFONYL]PHENYL]ETHYL]-2-METHOXYBENZAMIDE (GLYBURIDE)	2000-01-14	BRISTOL-MYERS SQUIBB COMPANY
74	IN213186A1	ININPCT2002603 MUM	2002-05-13	2008-01-25	A PHARMACEUTICAL COMPOSITION	1999-11-16	SMITHKLINE BEECHAM P.L.C.
75	IN209548A1	ININ-PCT2002393CHE	2002-03-14	2007-12-14	A PHARMACEUTICAL COMPOSITION FOR TREATMENT OF DIABETES	1999-09-17 2000-04-07 2000-08-26	M/S. NOVARTIS AG

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76	IN202817A1	IN42CHE2002	2002-01-18	2007-02-02	NOVEL ANTIBACTERIAL COMPOUNDS, PROCESS FOR THEIR PREPARATION AND PHARMACEUTICAL COMPOSITION CONTAINING THEM	2002-01-18	DR. REDDY'S LABORATORIES LTD.
77	IN218448A1	IN971CHE2001	2001-12-03	2008-05-23	NOVEL ALKOXY PROPIONIC ACID COMPOUNDS AND THEIR DERIVATIVES, PROCESS FOR THEIR PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM	2001-12-03	DR. REDDY'S LABORATORIES LTD.
78	IN204612A1	IN940MUM2001	2001-09-28	2007-06-15	DOSAGE FORM FOR TREATMENT OF DIABETES MELLITUS	2001-09-28	SUN PHARMACEUTICAL INDUSTRIES LTD.
79	IN211669A1	IN939MUM2001	2001-09-28	2008-01-25	A CONTROLLED RELEASE ANTIDIABETIC COMPOSITION	2001-09-28	SUN PHARMACEUTICAL INDUSTRIES LTD.
80	IN227341A1	IN917MUM2001	2001-09-24	2009-03-06	DOSAGE FORM FOR TREATMENT OF DIABETES MELLITUS	2001-09-24	SUN PHARMACEUTICAL INDUSTRIES LTD.
81	IN211460A1	ININPCT2001538 MUM	2001-05-09	2007-11-09	A PHARMACEUTICAL COMPOSITION	1998-11-12 1999-05-25	SMITHKLINE BEECHAM P.L.C.

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82	IN234701A1	IN301CHE2001	2001-04-09	2009-07-17	NEW MONOCYCLIC DERIVATIVES OF ARYL ACIDS, PROCESS FOR THEIR PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM	2001-04-09	DR. REDDY'S LABORATORIES LTD.
83	IN214114A1	ININPCT200133DEL	2001-01-16	2008-02-22	PREPARATION OF AQUEOUS CLEAR SOLUTION DOSAGE FORMS WITH BILE ACIDS	1998-07-24	SEO HONG YOO
84	IN209017A1	IN1124CHE2000	2000-12-26	2007-09-21	NOVEL OXAZOLIDINONE COMPOUNDS HAVING ANTIBACTERIAL PROPERTY, PROCESS FOR THEIR PREPARATION AND PHARMACEUTICAL COMPOSITIONS CONTAINING THEM	2000-12-26	DR. REDDY'S LABORATORIES LTD.
85	IN219534A1	ININPCT2000233 KOL	1999-02-16	2008-05-09	AN ORALLY ADMINISTERABLE GALENIC FORMULATION ALLOWING IMPROVED ABSORPTION BY THE TRANSMEMBRANE IN THE GASTROINTESTINAL TRACT	1999-02-16	MERCK PATENT GMBH.
86	IN225734A1	IN2088DEL1998	1998-07-20	2008-12-12	A PHARMACEUTICAL COMPOSITION COMPRISING COMPOUND I, SULPHONYLUREA AND BIGUANIDE ANTIHYPERGLYCEMIC AGENT	1997-07-18	SMITHKLINE BEECHAM P.L.C.

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Serial No.	**Patent Number**	**Application Number**	**Application/Filing Date**	**Publication Date**	**Title**	**Priority Date**	**Applicant Name**
1	IN390470A1	IN202121032098	2021-07-16	2022-03-04	FLOATING MICROPOROUS OSMOTIC TABLET	2021-07-16	DR PRABHA SINGH
2	IN365019A1	IN201841014660	2018-04-18	2021-04-23	ORAL DISINTEGRATING FILM COMPOSITIONS OF PARACETAMOL	2018-04-18	SHILPA MEDICARE LIMITED
3	IN383907A1	IN201717022449	2017-06-27	2021-12-10	CONTROLLED RELEASE OF ACTIVE SUBSTANCES	2017-06-27	SOCIETE DEXPLOITATION DE PRODUITS POUR LES INDUSTRIES CHIMIQUES SEPPIC
4	IN417421A1	IN201721021519	2017-06-20	2023-01-13	HOT MELT EXTRUDED/ GRANULATED DIRECTLY COMPRESSIBLE API'S/ EXCIPIENTS BY MELT GRANULATION TECHNOLOGY	2017-06-20	PURNIMA D. AMIN
5	IN416836A1	IN201721007863	2017-03-07	2023-01-06	PHARMACEUTICAL FORMULATION COMPRISING PARACETAMOL ESPECIALLY FOR PEDIATRICS	2017-03-07	MR SAGAR R. KINI, DR (MRS) SHILPA P. BHILEGAONKAR
6	IN361236A1	IN201747005459	2017-02-16	2021-03-19	ACID-ADDITION SALT OF TRK-INHIBITING COMPOUND	2017-02-16	ONO PHARMACEUTICAL CO., LTD.
7	IN360391A1	IN201647044193	2016-12-24	2021-03-12	PHARMACEUTICAL OIL IN WATER NANO-EMULSION	2016-12-24	SYNERGIA BIO SCIENCES PRIVATE LIMITED
8	IN352353A1	IN201621022853	2016-07-04	2020-12-04	PHARMACEUTICAL COMPOSITIONS CONTAINING MELT EXTRUDED IBUPROFEN AND FIXED DOSE COMBINATIONS THEREOF	2016-07-04	AMIN PURNIMA DHANRAJ, SINGH KARAN JASJIT

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9	IN348906A1	IN4578MUM2015	2015-12-04	2020-10-16	SELF MICRO-EMULSIFYING DRUG DELIVERY SYSTEM FOR COMBINATION THERAPY OF PARACETAMOL (PCM) AND VITAMIN E ACETATE	2015-12-04	BHAUMIK PANDYA, DR SHREERAJ SHAH, DR NIHAR SHAH
10	IN342779A1	IN523CHENP2015	2015-01-27	2020-07-31	INJECTABLE SUPERSATURATED ACETAMINOPHEN SOLUTION FOR SPINAL ADMINISTRATION	2015-01-27	SINTETICA S.A.
11	IN360017A1	IN245CHE2015	2015-01-16	2021-03-05	BENZIMIDAZAOLE DERIVATIVES OF PARACETAMOL AS POTENTIAL ANALGESIC, ANTIPYRETIC AND ANTI-INFLAMMATORY AGENTS	2015-01-16	M.S. RAMAIAH UNIVERSITY OF APPLIED SCIENCES
12	IN331352A1	IN5886CHE2014	2014-11-25	2020-02-07	SOFT GELATIN CAPSULE COMPOSITION OF ANTI-TUSSIVE AGENTS	2014-11-25	BIOLOGICAL E LIMITED
13	IN302878A1	IN5410DELNP2013	2013-06-17	2018-11-09	A FORMULATION COMPRISING A MELT- PROCESSED SOLID DISPERSION PRODUCT	2013-06-17	ABBVIE DEUTSCHLAND GMBH & CO. KG.
14	IN344465A1	IN2832DELNP2013	2013-04-01	2020-08-28	MICROENCAPSULATION PROCESS AND PRODUCT	2013-04-01	SPI PHARMA INC.
15	IN316307A1	IN8605DELNP2012	2012-10-04	2019-07-19	ACETAMINOPHEN COMPOSITION	2012-10-04	B. BRAUN MELSUNGEN AG
16	IN328090A1	IN7654DELNP2011	2011-10-05	2020-01-03	AQUEOUS PHARMACEUTICAL COMPOSITION	2011-10-05	FRESENIUS KABI DEUTSCHLAND GMBH

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17	IN317061A1	IN5955CHENP2011	2011-08-18	2019-08-02	CONTROLLED RELEASE PHARMACEUTICAL OR FOOD FORMULATION AND PROCESS FOR ITS PREPARATION	2011-08-18	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO A.C.R.A.F. S.p.A.
18	IN358983A1	IN78KOL2011	2011-01-20	2021-02-26	STABLE READY TO USE INJECTABLE PARACETAMOL FORMULATION	2011-01-20	UNI-PHARMA KLEON TSETIS PHARMACEUTICAL LABORATORIES S.A.,TSETI, IOULIA
19	IN266908A1	IN3568MUM2010	2010-12-30	2015-06-16	ANTIINFLAMMATORY COMPOSITION	2010-12-30	ZOTA HEALTH CARE LTD.
20	IN411067A1	IN630MUM2010	2010-09-09	2022-11-11	NOVEL COMPOSITION COMPRISING PARACETAMOL AND PROCESS FOR PREPARING THE SAME	2010-09-09	TROIKAA PHARMACEUTICALS LIMITED
21	IN298924A1	IN4577CHENP2010	2010-07-21	2018-07-20	A SLOW-RELEASE FORMULATION BASED ON AN ASSOCIATION OF GLYCOGEN AND ALGINATE	2010-07-21	AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO A.C.R.A.F. S.P.A.
22	IN345498A1	IN2955MUM2009	2009-12-22	2020-09-04	CONTROLLED RELEASE PHARMACEUTICAL COMPOSITION	2009-12-22	ABBOTT HEALTHCARE PRIVATE LIMITED
23	IN287452A1	IN4043DELNP2009	2009-06-19	2017-09-22	GALENICAL FORM FOR THE ADMINISTRATION OF PARACETAMOL BY TRANSMUCOUS MEANS	2009-06-19	PHILIPPE PEROVITCH, MARC MAURY

Details of Relevant Granted Patents of Paracetamol							
Paracetamol							
Serial No.	**Patent Number**	**Application Number**	**Application/Filing Date**	**Publication Date**	**Title**	**Priority Date**	**Applicant Name**
24	IN274817A1	IN262DELNP2009	2009-01-13	2016-08-10	ORAL LIQUID PHARMACEUTICAL COMPOSITION	2009-01-13	WYETH LLC
25	IN270935	IN4641KOLNP2008	2008-11-17	2009-03-13	PHARMACEUTICAL COMBINATION COMPRISING 3-(3-DIMETHYLAMINO-1-ETHYL-2- METHYL-PROPYL)-PHENOL AND PARACETAMOL	2006-04-28	GRUNENTHAL GMBH
26	IN285633A1	IN5229DELNP2008	2008-06-17	2017-07-28	ORAL THERAPEUTIC COMPOUND DELIVERY SYSTEM	2008-06-17	MCNEIL-PPC, INC.
27	IN241588A1	IN1374MUMNP2007	2007-09-10	2010-07-16	A CONSUMABLE FILM	1998-09-25	WARNER - LAMBERT COMPANY LLC
28	IN301189A1	IN3482DEL2005	2005-12-27	2018-09-28	MOUTH DISSOLVING PHARMACEUTICAL COMPOSITION AND PROCESS FOR PREPARING THE SAME	2005-12-27	JUBILANT GENERICS LIMITED
29	IN233919A1	IN3782DELNP2005	2005-08-25	2009-05-15	INJECTABLE LIQUID PHARMACEUTICAL COMPOSITION OF PARACETAMOL	2003-02-14	NGUYEN-XUAN THO
30	IN219706A1	IN703CHENP2005	2005-04-21	2008-07-04	CONTROLLED-RELEASE COMPOSITIONS	2003-10-10 2002-10-25	LABOPHARM EUROPE LIMITED LABOPHARM INC LABOPHARM (BARBADOS) LIMITED

Details of Relevant Granted Patents of Paracetamol							
Paracetamol							
Serial No.	**Patent Number**	**Application Number**	**Application/Filing Date**	**Publication Date**	**Title**	**Priority Date**	**Applicant Name**
31	IN243858A1	IN90MUM2005	2005-01-28	2010-11-12	SYNERGISTIC INJECTABLE COMBINATION OF ANTISPASMODIC AND ANTIPYRETIC - ANALGESIC	2005-01-28	SANJEEV KHANDELWAL
32	IN218972A1	IN69KOLNP2005	2005-01-20	2008-04-18	ORAL PHARMACEUTICAL FORMULATION IN THE FORM OF A PLURALITY OF MICROCAPSULES FOR PROLONGED RELEASE OF ACTIVE PRINCIPLE(S) WITH LOW SOLUBILITY	2002-07-26	FLAMEL TECHNOLOGIES
33	IN222973	IN1324MUM2004	2004-12-13	2006-07-21	A PHARMACEUTICAL ORAL DOSAGE FORM COMPRISING OF A NOVEL COMBINATION OF ACECLOFENAC, PARACETAMOL	2004-12-13	J.B. CHEMICALS & PHARMACEUTICALS LTD.
34	IN256010A1	IN2461DEL2004	2004-12-10	2013-04-19	PHARMACEUTICAL COMPOSITION FOR IMPROVING PALATABILITY OF DRUGS AND PROCESS FOR PREPARATION THEREOF	2004-12-10	COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH
35	IN225628A1	IN1296MUM2004	2004-12-06	2009-02-13	RESINATES OF CETIRIZINE AND LEVO-CETIRIZINE FOR TASTE MASKING	2004-12-06	THEMIS LABORATORIES PRIVATE LIMITED
36	IN206076A1	IN788MUM2004	2004-07-23	2007-07-13	AN ANTISPASMODIC AND AN ANALGESIC ANTIPYRETIC WITH AN ANTI-INFLAMMATORY AND ANALGESIC COMBINATION AND TO A METHOD OF MAKING THE SAME	2004-07-23	SANJEEV KHANDELWAL

Details of Relevant Granted Patents of Paracetamol							
Paracetamol							
Serial No.	**Patent Number**	**Application Number**	**Application/Filing Date**	**Publication Date**	**Title**	**Priority Date**	**Applicant Name**
37	IN208592A1	IN782MUM2004	2004-07-22	2007-08-31	A SYNERGISTIC ORAL SOLID FORMULATION CONTAINING ETORICOXIB AND PARACETAMOL AND METHOD FOR MAKING	2004-07-22	SANJEEV KHANDELWAL
38	IN230541A1	IN1483CHENP2004	2004-07-02	2009-03-27	TASTE MASKED AQUEOUS LIQUID PHARMACEUTICAL COMPOSITION AND A METHOD OF PREPARING THE SAME	2001-12-07	SANTOS, MA, JOYCE, BEDELIA, B SANTOS, RITA, JOSEFINA, M DEE, KENNIE, U
39	IN227968A1	IN1086CHENP2004	2004-05-17	2009-03-06	A PHARMACEUTICAL COMPOSITION COMPRISING PARACETAMOL AND A MASKING COMPONENT	2001-10-18	RECKITT BENCKISER HEALTHCARE (UK) LIMITED
40	IN221305A1	IN421CHE2004	2004-05-07	2008-09-12	A PROCESS FOR PREPARING SYNERGISTIC FIXED DOSE PHARMACEUTICAL COMPOSITION	2004-05-07	MEDREICH STERILAB LIMITED
41	IN226605A1	IN942DELNP2004	2004-04-12	2009-01-02	A PHARMACEUTICAL MULTI-PARTICULATE, TABLET OR PELLET	2001-10-15	HERCULES INCORPORATED
42	IN214002A1	IN304KOLNP2004	2004-03-09	2008-01-25	MICROPARTICULATE ORAL GALENICAL FORM FOR THE DELAYED AND CONTROLLED RELEASE OF PHARMACEUTICAL ACTIVE PRINCIPLE	2001-10-09	FLAMEL TECHNOLOGIES
43	IN218464A1	IN277MUM2004	2004-03-05	2008-10-03	AN ANTISPASMODIC ANALGESIC SYNERGISTIC FORMULATION FOR THE RELIEF OF PAIN IN AN ORAL SYRUP FORM	2004-03-05	SANJEEV KHANDELWAL

Details of Relevant Granted Patents of Paracetamol							
Paracetamol							
Serial No.	**Patent Number**	**Application Number**	**Application/Filing Date**	**Publication Date**	**Title**	**Priority Date**	**Applicant Name**
44	IN221923	IN206MUM2004	2004-02-23	2005-03-11	A PHARMACEUTICAL COMPOSITION BEING A SKELETAL MUSCLE RELAXANT WITH ANALGESIC AND A METHOD OF MAKING THE SAME	2004-02-23	SANJEEV KHANDELWAL INDIA
45	IN207877A1	IN208MUM2004	2004-02-23	2007-08-10	A SYNERGISTIC ANTISPASMODIC AND ANALGESIC FORMULATION AND TO A METHOD OF MAKING THE SAME	2004-02-23	SANJEEV KHANDELWAL
46	IN244585A1	IN198MUM2004	2004-02-20	2010-12-17	NOVEL DRUG DELIVERY SYSTEM	2004-02-20	TORRENT PHARMACEUTICALS LTD
47	IN238564A1	IN1525KOLNP2003	2003-11-24	2010-02-12	A NON-EFFERVESCENT DOSAGE FORM INTENDED TO BE SWALLOWED DIRECTLY SUCH AS A SWALLOW TABLET OR CAPSULE FORMULATION	2001-06-08	SMITHKLINE BEECHAM P.L.C.
48	IN221578A1	IN739KOLNP2003	2003-06-09	2008-06-27	METHOD AND COMPOSITIONS EMPLOYING FORMULATIONS OF LECITHIN OILS AND NSAIDS FOR PROTECTING THE GASTROINTESTINAL TRACT AND PROVIDING ENHANCED THERAPEUTIC ACTIVITY	2000-12-19	THE BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM
49	IN224550A1	IN418MUM2003	2003-04-28	2009-01-09	NOVEL FORMULATIONS OF NSAID FOR RECTAL USE	2003-04-28	M/S. LYKA LABORATORIES LIMITED

Details of Relevant Granted Patents of Paracetamol							
Paracetamol							
Serial No.	**Patent Number**	**Application Number**	**Application/Filing Date**	**Publication Date**	**Title**	**Priority Date**	**Applicant Name**
50	IN205996	IN58CHENP2003	2003-01-10	2005-04-08	A CONTROLLED RELEASE PHARMACEUTICAL TABLET CONTAINING CROSS-LINKED AMYLOSE AND A PROCESS FOR PREPARING CROSS-LINKED AMYLOSE	2000-06-29	M/S. LENAERTS VINCENT, BECK ROLAND HERWIG FRIEDRICH, BOGAERT ELSIE VAN, CHOUINARD FRANCOIS, ET AL.
51	IN206214A1	ININPCT2002179 4MUM	2002-12-13	2007-07-13	ANALGESIC AND ANTI-INFLAMMATORY COMPOSITIONS CONTAINING COX-2 INHIBITORS	2000-06-13	WYETH
52	IN220289A1	ININPCT20021229 KOL	2002-09-27	2008-05-23	A PHARMACEUTICAL COMPOSITION WITH IMMEDIATE AND SUSTAINED RELEASE PHASE OF PARACETAMOL	2002-09-27	SMITHKLINE BEECHAM P.L.C.
53	IN209325A1	ININPCT2002186 MUM	2002-02-14	2007-09-21	DIRECTLY COMPRESSIBLE, ULTRA FINE ACETAMINOPHEN COMPOSITIONS AND PROCESS FOR PRODUCING SAME	1999-09-16	RHODIA, INC.
54	IN207623A1	ININPCT2002187 CHE	2002-02-04	2007-11-02	PHARMACEUTICAL COMPOUNDS	1999-08-12	M/S. NICOX S.A.
55	IN212550	ININPCT2001600 DEL	2001-07-05	2002-04-13	COMPOSITIONS HAVING IMPROVED DELIVERY OF ACTIVES	2001-07-05	THE PROCTER & GAMBLE COMPANY

Details of Relevant Granted Patents of Paracetamol							
Paracetamol							
Serial No.	**Patent Number**	**Application Number**	**Application/Filing Date**	**Publication Date**	**Title**	**Priority Date**	**Applicant Name**
56	IN213827A1	IN288DEL2000	2000-03-22	2008-01-25	A NOVEL ANTISPASMODIC COMPOSITION	2000-03-22	PANACEA BIOTEC LIMITED
57	IN221334A1	IN15DEL2000	2000-01-11	2008-08-01	MICROCAPULES OF RESERVOIR KIND CONTAINING AT LEAST ONE MEDICINAL AND NUTRITIONAL ACTIVE PRINCIPLE (AP)	1994-10-18	FLAMEL TECHNOLOGIES
58	IN217045A1	IN1160CHE1999	1999-12-01	2008-05-23	AN IMPROVED FAST ACTING ORAL PHARMACEUTICAL COMPOSITION AND A PROCESS FOR ITS PREPARATION	1999-12-01	NATCO PHARMA LIMITED
59	IN223508A1	IN438CHE1998	1998-03-04	2008-11-21	A SWALLOW TABLET OR CAPSULE FORMULATION	1997-03-05	SMITHKLINE BEECHAM P.L.C.
60	IN212060A1	IN791DEL1996	1996-04-12	2007-11-30	ORAL ANTI-SPASMODIC ANTI-INFLAMMATORY COMPOSITION COMPRISING PITOFENONE, FENPERINIUM AND NSAID	1996-04-12	PANACEA BIOTEC LIMITED

Annex 2
Detailed Information on the Metformin and Paracetamol Patents Analyzed in the Case Studies

METFORMIN PATENT

Patent No. 438281, granted to Windlas Biotech Ltd, an Indian pharmaceutical company, was published on 14 July 2023.

The patent covers a single-layer fixed-dose tablet composition of three active ingredients, extended-release metformin, voglibose and glimepiride, useful for treating type 2 diabetes mellitus by administering the composition to a patient in need thereof.

The inventive concept was claimed in a low-weight tablet reducing the longer axis of the tablet to less than or equal to 17mm and the shorter axis to less than or equal to 6mm, which makes it more amenable for prescription to geriatric patients.

The patent application was examined and objected to on the following grounds by the Patent Office:

- Lack of inventive step [S.2(1)(ja) of the Patents Act]
- New form of an existing substance [S.3(d)]
- Lack of clarity of claims [S.10(5)]
- Insufficient disclosure [S.10(4)].

The Patent Office raised objections stating that the present invention lacked inventive step under Section 2(1)(ja) of the Patents Act. Prior art 1 (European patent publication No. EP3315124 A1) disclosed a bilayer fixed-dose combination of extended-release metformin with dapagliflozin. Prior art 2 (Indian patent application No. IN-MUMNP-2007-00151A) disclosed a fixed-dose combination of extended release of metformin, voglibose and glimepiride. The invention lacked inventive step when prior art 1 was combined with prior art 2.

The patentee argued that the present invention had a low weight, acceptable size and shape, and exhibited superior chemical and physical stability with extended release of metformin. Hence it was not obvious to a person skilled in the art and therefore possessed inventive step.

The Patent Office also objected to the invention under Section 3(d) of the Patents Act, stating that it was a mere discovery of a new form of a known substance which did not result in enhancement of the known efficacy of that substance.

The patentee argued that the present invention resulted in significant differences in safety and/or efficacy by decreasing the size of the tablet. Therefore, it was not a mere discovery of a new form of a known substance.

Analysis

Objection on Lack of Inventive Step

The applicant failed to demonstrate any technical advance over the combination of prior arts 1 and 2. In particular, no technical advance was demonstrated over prior art 2. The Patent Office failed to identify the closest prior art. Prior art 2, not prior art 1, was the closest prior art as it disclosed the combination of all the three active ingredients of the present invention. No data on superior chemical or physical stability was demonstrated by the applicant. It only mentioned that the dissolution profile was comparable with the marketed products.

Interestingly, while raising the inventive-step objection, the Patent Office did not consider the admission on the part of the applicant (page 6, lines 16 to 18 of the patent specification) regarding the availability of four marketed formulations of bilayer tablets having the same combination of the three active ingredients. The only difference of the present product was in terms of the shorter physical dimensions of the tablet and its single-layer instead of bilayer form. However, even though it was single-layer, two of the active ingredients were applied as two coatings on the third active ingredient.

Not all the steps in the five-step test prescribed in *F. Hoffmann-La Roche v. Cipla* (2015) were applied to evaluate inventive step. The five-step test is also prescribed by the Manual of Patent Office Practice and Procedure (version 3.0, 2019, p. 86). Steps 1 to 3 of the test were not applied, and step 4 was only partly applied. The person skilled in the art relevant to the invention was not identified as per step 1. Neither was the inventive concept of the invention established as per step 2. The common general knowledge of the skilled person relevant to the invention was also not identified as per step 3.

The reduction in the physical dimension of the tablet was the only change existing when compared with prior art 2. Such a change cannot be deemed as a technical advance. Therefore, the invention would lack inventive step.

Objection on New Form of an Existing Substance

The applicant failed to demonstrate enhanced therapeutic efficacy over the existing substance. The Supreme Court's Novartis judgement categorically states that effi-

cacy in the context of a medicine can only be therapeutic efficacy (paragraph 180). The existing or known substance was not identified by the Patent Office in the case of the present invention. Prior art 2 can be considered as the known substance. The Patent Office should have demanded that the applicant demonstrate enhanced therapeutic efficacy of the present invention over prior art 2. No such data was demonstrated. Instead, the applicant was able to overcome the objection on the grounds of the invention's physical properties/appearance. However, it is clear from the Novartis judgement (paragraph 187) that physico-chemical properties cannot be considered for the purpose of examining therapeutic efficacy in the context of Section 3(d).

Failure to Raise Objection Under Section 3(e)

The present invention was a single-layer fixed-dose pharmaceutical combination of three active ingredients. Nevertheless, the Patent Office failed to raise an objection under Section 3(e), which bars patentability of combinations which result only in aggregation of the properties of the components.

PARACETAMOL PATENT

Patent No. 416836, granted jointly to two inventors of Indian origin, Mr Sagar R. Kini and Dr (Mrs) Shilpa P. Bhilegaonkar, was published on 6 January 2023. The patent covers a ready-to-use liquid paediatric composition of paracetamol with three other, inactive ingredients/excipients, viz., an oil phase, a surfactant and a co-surfactant. Maisine 35-1, Cremophor EL and Transcutol were selected as the oil phase, surfactant and co-surfactant respectively.

The inventive concept of the formulation, according to the patentee, lay in the better drug loading capacity of paracetamol, a synergistic effect due to a particle size of less than 10nm of paracetamol dispersion, reducing the volume of administration of paracetamol (250mg/2ml or 120mg/1ml) as compared with marketed formulations (240mg/5ml), and absence of use of water as solvent, which leads to paracetamol stability.

The patent application was examined and objected to on the following grounds by the Patent Office:

- Lack of inventive step [S.2(1)(ja)]
- New form of an existing substance [S.3(d)]
- Mere admixture of known components [S.3(e)]
- Lack of clarity of claims [S.10(5)].

The Patent Office objected that the present invention lacked inventive step in light of prior arts 1 (PCT international publication No. WO 2004041249) and 2 [Naser M. Hasan et al., "Flavored Self Microemulsifying Lipid Formulations for Masking the Organoleptic Taste of Pharmaceutical Actives" (2015), 5(11) *Journal of Applied Pharmaceutical Science*, 127]. In the hearing notice, two additional prior arts 3 (PCT international publication No. WO2015198350) and 4 (Korean patent publication No. KR20040013286) were cited by the Patent Office based on the claim amendments made by the applicant after filing a response to the First Examination Report. In light of prior arts 1 to 4, the invention was held to lack inventive step. Prior art 1 disclosed a microemulsion concentrate comprising a water-insoluble anti-cold drug, a surfactant and an oil. One of the embodiments disclosed the anti-cold drug as paracetamol. Prior art 2 disclosed a stable flavoured oil/water-based paracetamol microemulsion comprising various oils such as hydrogenated castor oil, co-surfactants such as Glycerox 767 HC, Crodamol PC, oil/aqueous-based flavours and non-ionic surfactants. Prior art 3 disclosed a pharmaceutical emulsion of paracetamol encased in monounsaturated fatty acid droplets along with a co-surfactant. Prior art 4 disclosed an acetaminophen (another name for paracetamol) composition having a surfactant, co-surfactant and oil.

The applicant pointed to the better drug loading capacity of paracetamol, a synergistic effect due to particle size of less than 10nm of paracetamol dispersion, reducing the volume of administration of paracetamol (250mg/2ml or 120mg/1ml) as compared with marketed formulations (240mg/5ml), and absence of use of water as solvent, which leads to paracetamol stability. Hence, the invention was said to demonstrate technical advance and to be non-obvious to a person skilled in the art. Therefore, the subject matter was held to be inventive.

The paediatric formulation of paracetamol was considered to be a mere new form of a known substance, and hence the said claims also attracted Section 3(d) of the Patents Act as per the examination report. Paracetamol was identified to be the known substance and the paediatric formulation as the mere new form. Hence it would be non-patentable under Section 3(d).

The applicant argued that since the subject matter was inventive, it did not fall under Section 3(d) and the paediatric formulation of paracetamol was not a mere discovery of a new form of a known substance.

In addition, the examiner raised objections stating that the formulation was a mixture of known ingredients having known properties where the mixture did not result in synergism and hence was non-patentable under Section 3(e).

The applicant argued that the formulation possessed synergistic effect by virtue of better drug loading capacity of paracetamol, particle size of less than 10nm of paracetamol dispersion, reducing the volume of administration of paracetamol (250mg/2ml or 120mg/1ml) as compared with marketed formulations (240mg/5ml), and absence of use of water as solvent, which leads to paracetamol stability.

Analysis

Objection on Lack of Inventive Step

The five-step test of *Roche v. Cipla* was either not applied or only partly applied while examining the inventive-step requirement. The test is also prescribed by the Manual of Patent Office Practice and Procedure (version 3.0, 2019, p. 86) for examining inventive step. The person skilled in the art relevant to the invention was not identified as per step 1 of the test. The inventive concept of the invention was not established as per step 2. The common general knowledge of the skilled person relevant to the invention was not identified as per step 3. The difference between the prior arts and the subject matter of the present invention was not established. The objection did conclude that there was no inventive step. However, it merely stated that by combining prior arts 1 and 2 it would be obvious to a person skilled in the art, without citing how it could be deemed obvious.

Objection on New Form of an Existing Substance Under Section 3(d)

The applicant failed to demonstrate enhanced efficacy over the known substance. It is clearly mentioned in the Novartis judgement that efficacy in the context of a medicine can only be therapeutic efficacy (paragraph 180).

The applicant argued that the invention did not attract Section 3(d) as it was inventive. Surprisingly, this ground is being commonly used to overcome objections under Section 3(d) and 3(e). However, therapeutic efficacy can be established only by demonstrating pharmacological data. The applicant failed to provide evidentiary support for enhanced efficacy.

Objection Under Section 3(e)

The applicant failed to demonstrate synergism of the paediatric paracetamol formulation when paracetamol was combined with the three other ingredients, viz., Maisine 35-1, Cremophor EL and Transcutol. In the case of medicines, synergism must be established using pharmacological data, which would have to be supported by *in vitro* or *in vivo* studies in biological systems.

The synergism between paracetamol and the three inactive ingredients can be demonstrated by first determining the activity of each component and then comparing it with the activity of the combination. If the combination demonstrates greater pharmacological activity than the sum of the individual activities of each component, then it will be not considered a mere admixture.

Threefold data was provided in the patent specification and the response to the First Examination Report to argue that the paediatric formulation of paracetamol demonstrated synergism. This included sufficient drug loading capacity of paracetamol in the formulation, better stability in terms of smaller particle size and zeta potential and *in vitro* solubility enhancement studies to demonstrate faster drug release of paracetamol compared with conventional dosage forms.

However, in the present invention, the comparison of the pharmacological activity of the paediatric formulation of paracetamol should have been made with the activity of paracetamol alone and the individual activity, if any, of the inactive ingredients. Mere improvement in physico-chemical properties such as stability, solubility, drug loading or release profile may not by itself establish synergistic pharmacological action unless it is demonstrated that the combined formulation exhibits greater therapeutic efficacy or pharmacological activity than the sum of the individual effects of its components.

Failure to Raise Objection Under Section 10(4)(a)

The Patent Office failed to raise an objection under Section 10(4)(a) regarding insufficient disclosure. Though it disclosed a broad range of the three excipients along with paracetamol, the patent specification failed to disclose a general process of making the paediatric pharmaceutical formulation of paracetamol, nor did it disclose a specific process. Secondly, even though it disclosed a pharmaceutical composition of paracetamol formulation without forming precipitates in the presence of water (page 6 of the specification, paragraph 4), it did not provide any experimental support for the findings. Thirdly, it disclosed that the paracetamol formulation of the present invention resulted in the formation of nanoemulsion *in vivo* but failed to disclose any *in vivo* data to substantiate the claim. Thus, the specification did not enable a person with average skill and knowledge to make the paracetamol paediatric formulation.

Failure to Provide Substantive Reasoning

The Indian Patent Office's order did not provide the reasoning for why the patent was granted. Neither did it explain how the substantive objections regarding inventive step, Section 3(d) and 3(e) were overcome.

Annex 3
Independent Claims in the Two Abovementioned Metformin and Paracetamol Patents

Claim on Metformin

A single-layer coated tablet composition comprising:

a) an extended-release matrix core comprising metformin or salts thereof along with one or more rate-controlling polymers selected from the group consisting of carboxymethyl cellulose, methyl cellulose, hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), hydroxyethyl cellulose, hydroxyethyl methylcellulose or combinations thereof and excipients;

b) first functional coating layer comprising voglibose and/or glimepiride along with one or more pharmaceutically acceptable excipients; and

c) second functional coating layer over first coating layer comprising voglibose and/or glimepiride along with one or more pharmaceutically acceptable excipients;

wherein the total weight of metformin, voglibose and glimepiride is 70–90% of the total composition and the total weight of the rate-controlling polymers and excipients used is 10–30% of the total weight of composition; wherein the composition provides an extended release of metformin for at least 12 hours; and wherein the longer axis of the tablet is less than or equal to 17mm and the shorter axis is less than or equal to 6mm before immersion of the said tablet in water.

Claim on Paracetamol

A pharmaceutical formulation comprising paracetamol for paediatrics, characterized in that: said formulation consisting of 10% w/w paracetamol; lipid phase glyceryl monolinoleate NF 9% w/w, surfactant PEG-35 castor oil 48.6% w/w, and co-surfactant diethylene glycol monoethyl ether NF 32.4% w/w.

Manufacturing Patents: A Study on Metformin and Paracetamol Patents in India

The practice of patent evergreening – obtaining multiple patents on incremental modifications to known substances – can unduly extend a patentee's monopoly on a product and impede market competition. India has instituted in its patent law safeguards against evergreening that restrict patentability only to products which demonstrate genuine innovation or enhanced efficacy.

However, this paper reveals that, in the case of pharmaceuticals, these safeguards have often been inadequately and inconsistently applied, resulting in wrongful patent grants. Taking the examples of the antidiabetic metformin and the analgesic paracetamol, the study finds that 146 product patents were issued in India between 2005 and 2023 for various formulations of two medicines already in use for over 70 years.

The proliferation of patents covering known substances raises questions of accountability within the Indian patent system and could, if left unaddressed, hinder access to medicines, stifle growth of the domestic pharmaceutical sector and undermine India's status as "the pharmacy of the developing world".

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